12th Biosimilars Congregation 2018

"Uniting industry leaders to analyse advanced commercial developments & to identify successful management strategies of Biosimilars"

27th & 28th February 2018,
Holiday Inn, Kensington High Street,
London, UK

#VIbsc

AGENDA AT A GLANCE

Key Speakers Include

NIRAJ CHHAYA
Senior Risk Management Physician of Biosimilar Compounds
Boehringer Ingelheim

THOMAS SACHNIK
Senior Manager Strategic Associate to the President & CEO Generics Europe
Teva Pharmaceuticals

SUE NAEYAERT
Global Head Pricing, Market Access, Government Affairs and Policy Biosimilars
Fresenius Kabi SwissBioSim

CHRISTIAN AGBOTON
Sr Global Brand Medical Director - Global Medical Affairs
Takeda

KAUSTUBH BERDE
Vice President - International Business : Emerging Markets
Wockhardt

CORNELIA ULM
VP Regulatory Affairs Biosimilars
Biotec Regulatory Consulting GmbH (former Fresenius Kabi SwissBioSim GmbH)

HANMANT BARKATE
Vice President & Head Medical Services
Glenmark

ANNA AILLERIE
Director, Commercial Biosimilars EMEA
Lupin

LIZ POLLITT
Director
BPCRCS

FREDRIK SUNDBERG
Director Strategic Customer Relations
GE Healthcare

BER OOMEN
Expert Member Health Care Professionals
European Medicines Agency

MAARTEN VAN BAELEN
Market Access Director
Medicines for Europe

LOUIS BOON
CSO
Bioceros

PETER JORGENSEN
CEO
Danish Generic and Biosimilar Medicines Industry Association (IGL)

ANDREAS HERRMANN
CEO
ValeriusBio

VLADIMIR ZAH
CEO
ZRx Outcomes Research (Canada)

ROBERT A. JOHNSTONE
Board Member
International Alliance of Patients Organisations

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency

OMAR ALI
Visiting Lecturer, University of Portsmouth & Former Adviser
NICE

FEDERICO POLLANO
Director Contract Manufacturing and BD
Polpharma Biologics

ALEX KUDRIN
Independent Consultant and clinical expert

DIVYA CHADHA MANEK
Head of BD (Commercial)
NHS - NIHR Clinical Research Network

PAUL CALVO
Director
Sterne, Kessler, Goldstein & Fox (USA)

AIDAN FRY
Editor
Generics Bulletin

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

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"New topic to organize by virtue insight appreciate your choice of current hot topics participated as a deligate with inquisitiveness to learn more biosimilars mission accomplished"

HEAD PV, BMS INDIA

AGENDA AT A GLANCE

ANNA FORSYTHE
Managing Partner
Purple Squirrel Economics (USA)

MARIE MANLEY
Partner, Head of the Regulatory Practice
Bristows

JACQUELINE MULRYNE
Counsel
Arnold & Porter

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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"The only way to stay up to speed in this fast evolving market is to touch base with your peers. The biosimilars congregation is the right place to do it"

Global Brand Manager & Global Biosimilars Business Intelligence, Merck Serono

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

The biosimilar impact is coming - The coming wave of biosimilars, which are essentially generic versions of expensive biologic drugs, are about to take a chunk of sales away from big pharmaceutical companies. The development of the Biosimilars market is growing exponentially with the industry forecast to be worth $25 billion by 2020. To date, EMA has approved 38 biosimilars. Three biosimilar approvals have been withdrawn, this leaves a total of 35 biosimilars approved for use in Europe.

The Biosimilars market is going to heat up considerably over the next three years. Biosimilar versions of a number of major biologic drugs used in the treatment of cancers and rheumatic diseases are expected to complete their development and potentially come on to the market. In order to ensure the sustainability of public healthcare systems, in the context of ageing populations and the growing number of diagnosed chronic diseases, it will be essential to harness the potential of Biosimilars to deliver savings, so that greater numbers of patients can be treated with these medicines.

Our 12th Biosimilars Congregation 2018 will provide insight into the current state of play in the EU and stimulate debate, in a multi-stakeholder setting, on the vital role of biosimilar medicines in the sustainability of healthcare systems. Beyond a comprehensive outlook of key European market access policies, our speakers will outline the key recent developments in regulatory science and regulatory policy in the EU and other international jurisdictions. Special emphasis will be placed on strengthening the link between regulators and medical communities as an essential basis for greater understanding and acceptance of biosimilar medicines. This Biosimilars conference will focus on multiple aspects of Biosimilar product development to successfully deliver safe, Biosimilar products to the market place. By attending this conference, you will gain a comprehensive outlook on the key issues surrounding Biosimilars. This event will provide an important platform for Biosimilars stakeholders to discuss and share best practices in furthering Biosimilars development.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 12th Biosimilars and Congregation 2018.

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Strategies for market access and expansion by identifying key changes and future projections in biosimilars
- Brexit and Biosimilars
- Current market trends and future challenges for Biosimilar success
- A Clinician's Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability
- Current challenges and opportunities - strategies to develop Biosimilars
- Payer perspective on biológics and Biosimilars
- Biosimilar Interchangeability: The newest regulation
- Biosimilar, biobetter and next generation therapeutic antibodies
- Guidance on interchangeability laws, patient litigation and IP rules
- CMC, Preclinical and clinical considerations for Biosimilars and Follow-on Biologics
- Impact of Technology
- Know the challenges of Biosimilar manufacturing
- Gain in-depth knowledge on role of technology transfer - How does this effect market access?
- Biosimilars development and impact on clinical practice
- Hear case studies on biosimilars drug development from pre-clinical to clinical and the various testing required such as immunogenicity and bio-similarity tests
- Production of biosimilar MAbs
- Research-based industry Biosimilar strategies
- Considerations for the analytical similarity assessments when designing a Biosimilar development program
- Determining the right investments & potential returns from Biosimilars
- Latest developments in regulation to increase speed of entry and compliance
- Future of next generation biosimilars
- Be part of a major networking opportunity

AN EVENT TO VOW

Get more from the event, 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

CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, and Senior Scientists from the following roles:

Biopharmaceuticals/ Biotherapeutics, Follow on Biologics/Follow on Proteins/Biosimilars, Biologics/Biotechnology/Biogenerics, Legal Affairs, Intellectual Property, Health Economics, Pricing and Reimbursement, Clinical Immunology, Principal Scientist, Chief Scientific Officer, Process Control and Analytical Technologies, Analytical Characterisation, Regulatory Compliance, Pharmacovigilance, Drug Safety & Risk Management, Quality Affairs/ Quality Control, New Product Development, Process Science, Portfolio Management, Research & Development, Business Development, Business Operations, Scientific Affairs, Commercial Affairs, Marketing

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"Good Discussion about commercial Challenges and lessons with 1st class biosimilar products and challenges/ development, regulatory and commercial with biosimilars MABs"

Medical Assessor in Licensing of Biological Products, MHRA

AGENDA AT A GLANCE

DAY ONE - 27th February 2018

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

09:20 LOUIS BOON
CSO
Bioceros

Chairperson opening remarks

MARKET OVERVIEW & ANALYSIS

09:30 THOMAS SACHNIK
Senior Manager Strategic Associate to the President & CEO Generics Europe
Teva Pharmaceuticals

The biosimilar business case

- The profitability of the biosimilar business and its sustain ability remains a major question mark for the corporate decision makers in pharma
- The past has shown a variety of partnerships in the field driven by a high degree of uncertainty of the business model of biosimilars – While investments are high and returns uncertain, risk is shared by partnerships and collaborations along the entire value chain of biosimilars
- Comparing the biosimilar waves, how will the business case change and how did and will the competitive landscape evolve?

PAYER'S PERSPECTIVE

10:00 OMAR ALI
Visiting Lecturer, University of Portsmouth & Former Adviser, NICE

Integration, Assimialtion, Value based offerings and Future landscapes

10:30 KAUSTUBH BERDE
Vice President - International Business : Emerging Markets
Wockhardt

Cost vs Quality: What's the best strategies for Emerging Markets

- Exploring biosimilar opportunities in Emerging Markets
- Exploring market entry strategies in addressing differences in biosimilar regulation
- Understanding the changing market dynamic and landscape in emerging markets

11:00 - Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

11:20 Keynote Panel Discussion: Challenges & Opportunities - Consequences of Brexit on Biosimilars

- Biosimilar Interchangeability
- Preparing for the Implications of "Brexit" in the Pharmaceutical Industry
- A difficult road ahead for a "Pure-Play" Biosimilar maker
- How to strengthen biosimilar medicine developers in Europe
- Biosimilars and Biobetters - Manufacturing and Bio-analytics
- Future of next generation biosimilars
- The key roles & responsibilities of pharmacists in biosimilars development
- Biosimilars Policy "By Year End"

Moderator :

LOUIS BOON
CSO
Bioceros

Panellist :

OMAR ALI
Visiting Lecturer, University of Portsmouth & Former Adviser, NICE

DIVYA CHADHA MANEK
Head of BD (Commercial)
NHS - NIHR Clinical Research Network

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

AIDAN FRY
Editor
Generics Bulletin

12:00 HANMANT BARKATE
Vice President & Head Medical Services
Glenmark

Clinical strategies for development of Biosimilars

- In the development of Biosimilars, clinical strategies should aim to resolve uncertainties that may remain post preclinical development regarding the similarity of proposed biosimilar with the reference product.
- Pharmacokinetic and pharmacodynamics studies create a sound scientific platform to design early phase as well as late phase clinical trials for biosimilars .
- Phase 3 clinical trials should demonstrate that difference in efficacy or safety between proposed biosimilar and reference product is less than of pre-specified margin of clinical equivalence .

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"I think the event was great and really threw insight on positioning biosimilars vis a vis other drugs on the regulatory side in India and World and what are challenges faced by industry as well as government and also regulators It was a great learning"

AVP & Head Legal, Wockhardt

AGENDA AT A GLANCE

DAY ONE - 27th February 2018

- Biosimilar guidelines issued by various regulatory authorities or WHO do not provide standard equivalence margins for most biologicals used to detect clinically meaningful differences in the targeted diseases.
- The equivalence margins should be considered on a case-by-case basis, and regulators may recommend a different margin than that proposed by sponsors.

12:30 – **Networking luncheon**

13:30 **DIVYA CHADHA MANEK**
Head of BD (Commercial)
NHS - NIHR Clinical Research Network

Current challenges and opportunities - strategies to develop Biosimilars

- The usual suspects - a unique UK challenge
- A UK strategy to drive delivery of biosimilar clinical trials - the Network approach
- Facilitating success - case study examples of working with the biosimilars industry
- Changing attitudes, appetite and acceptance in the NHS

SAFETY AND RISK MANAGEMENT PLANNING

13:50 **STEINAR MADSEN**
Medical Director
Norwegian Medicines Agency

Biosimilars – savings and sustainability

- To switch or not to switch – to be or not to be?
- The winner takes all – the problem of the second entrant
- Are we throwing money out of the window?

COMMERCIALISATION & MARKET ACCESS

14:30 **Panel Discussion: The commercial landscape and market access for Biosimilars: Planning in an uncertain environment**

- Comparison of US/EU biosimilar guidelines
- Sustainability defined by the Stakeholders securing the future of healthcare
- Challenges and obstacles faced by manufacturers in developing biosimilars
- Bringing the next generation of Biosimilars to the market
- Biobetters: Market access opportunity?
- Evidence generation will be the key to future success

Moderator :

LOUIS BOON
CSO
Bioceros

Panellist :

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency

SUE NAEYAERT
Global Head Pricing, Market Access, Government Affairs and Policy Biosimilars
Fresenius Kabi SwissBioSim

ANNA AILLERIE
Director, Commercial Biosimilars EMEA
Lupin

FREDRIK SUNDBERG
Director Strategic Customer Relations
GE Healthcare

ANNA FORSYTHE
Managing Partner
Purple Squirrel Economics (USA)

15:10 - **Afternoon Tea/Coffee**

15:30 **MAARTEN VAN BAELEN**
Market Access Director
Medicines for Europe

Biosimilars – Of all experience – What have we learnt? What are the challenges ahead?

- Biosimilars market access and penetration in the current era – Considerations for providers, payers, prescribers and patients
- Exploring government pricing and reimbursement policy challenges associated with biosimilars
- Commercial potential and suceceful ways on how to gauge such an opportunity in biosimilar
- The pricing and reimbursement of biosimilars in EU, US and Asia?
- Why biosimilars are different to generics from a market access and impact perspective

16:10 **ROBERT A. JOHNSTONE**
Board Member
International Alliance of Patients Organisations

Topic TBC

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"All the topics picked up very good and were pretty informative. The panel discussions brought very nice views and insights on agenda points"

Business Development & PM, Lupin Biotech

AGENDA AT A GLANCE

DAY ONE - 27th February 2018

16:40 BER OOMEN
Expert Member Health Care Professionals
European Medicines Agency

Switch management in Bio-Similar: Education of Nurses and collaboration in interdisciplinary context

- Introduction in Nurses Guideline on Switch Managament
- Patient safety in health means a collaborative and interdisciplenary approach
- Continuing Professional Development for nurses on biosimilar medication: a shared responsebility

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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"Excellent event. It did meet our expectation in term of complete representation of the biosimilar development"

Senior Manager, Regulatory Affairs, Sanofi

AGENDA AT A GLANCE

DAY TWO - 28th February 2018

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

09:30 LOUIS BOON
CSO
Bioceros

Chairperson opening remarks

COMMERCIALISATION & MARKET ACCESS

09:40 SUE NAEYAERT
Global Head Pricing, Market Access, Government Affairs and Policy Biosimilars
Fresenius Kabi SwissBioSim

Topic TBC

MANUFACTURING

10:10 LOUIS BOON
CSO
Bioceros

Know the challenges of Biosimilar, Biobetters manufacturing

- Best Practices for a competitive Market
- Antibody and Biosimilar Manufacturing
- Opportunities for Additional Industry Insight
- Improving the Functional Characterization of Biosimilars
- Biosimilar Milestone

10:40 – Morning Coffee/Tea & Discussion

BUSINESS MODELS

11:00 ANDREAS HERRMANN
CEO
ValeriusBio

Differentiation as success factor for biosimilars

- Different approaches to avoid the main stream
- Reduce competition
- How to differentiate

11:30 – Solution Provider Presentation

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11:50 – Solution Provider Presentation

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CLINICAL

12:10 NIRAJ CHHAYA
Senior Risk Management Physician of Biosimilar Compounds
Boehringer Ingelheim

Clinical considerations and challenges in pharmacovigilance for biosimilars

- Pharmacovigilance: During clinical development and post-marketing phases
- Key topics: Immunogenicity, Interchangeability, Risk management
- Real world evidence

12:40 - Networking luncheon

13:40 FEDERICO POLLANO
Director Contract Manufacturing and BD
Polpharma Biologics

Case Study - Lean and cost efficient mAB production set up

- Set up state of the art biopharmaceutical development and production in Europe
- Cell culture and bacterial platform for internal and external customers
- Modular/Flexible/Lean
- Covering of the whole value chain from the cell line development up to large scale production
- Costs of goods estimation from the very beginning

14:10 VLADIMIR ZAH
CEO
ZRx Outcomes Research (Canada)

Market access strategies for Biosimilars – Different strategies need to be deployed in different parts of the world

14:40 PETER JORGENSEN
CEO
Danish Generic and Biosimilar Medicines Industry Association (IGL)

The Danish way to a high uptake – a blueprint?

- The role of science
- The role of the Health Authorities
- The role of payers, tenders and pricing
- The role of stakeholder participation
- The role of information to patients

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"The presentations were informative and the panel discussions engaging, covering key and important topics of debate. The food and wine reception were excellent and allowed for relaxed networking opportunities"

Director, Voisin Consulting Life Sciences

DAY TWO - 28th February 2018

15:10 CHRISTIAN AGBOTON
Sr Global Brand Medical Director - Global Medical Affairs
Takeda

Biosimilars: anatomy of a quiet clinical revolution

- Impact of biosimilars in clinical setting: what is the evidence so far?
- Interchangeability among biosimilars: Is it the future?
- Biosimilars or new MoA: what's best?

15:40 – Afternoon Tea/Coffee

16:00 ALEX KUDRIN
Independent Consultant and clinical expert

Biosimilar development: analytical and clinical challenges. Pitfalls and lessons learned

- Limitations of analytical and clinical tools: what is the path forward?
- Oncology Mab biosimilar advances and difference in dynamics
- Future trends and forecast of biosimilar market.

REGULATION OVERVIEW & UPDATE

16:30 Panel Discussion: The developing regulatory frame work in advanced and developing markets – for Today & Tomorrow

- Highlighting the Differences between EU and USA in Terms of regulatory Requirements
- Intellectual property and regulatory interplay in biosimilars
- How regulators, payers and policy makers take initiatives to make healthcare more sustainable
- Policy practices to maximise social benefit from Biosimilars
- Regulatory changes necessary to maximize biosimilars potential
- The way forward

Moderator :

LOUIS BOON
CSO
Bioceros

Panellist :

CORNELIA ULM
VP Regulatory Affairs Biosimilars
Biotec Regulatory Consulting GmbH (former Fresenius Kabi SwissBioSim GmbH)

MARIE MANLEY
Partner, Head of the Regulatory Practice
Bristows

JACQUELINE MULRYNE
Counsel
Arnold & Porter

LIZ POLLITT
Director
BPCRCS

PAUL CALVO
Director
Sterne, Kessler, Goldstein & Fox (USA)

17:10 - Chairperson's closing remarks and end of conference

17:15 End of the 12th Biosimilars Congregation 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.

Sponsorship Enquires - sponsor.uk@virtueinsight.com

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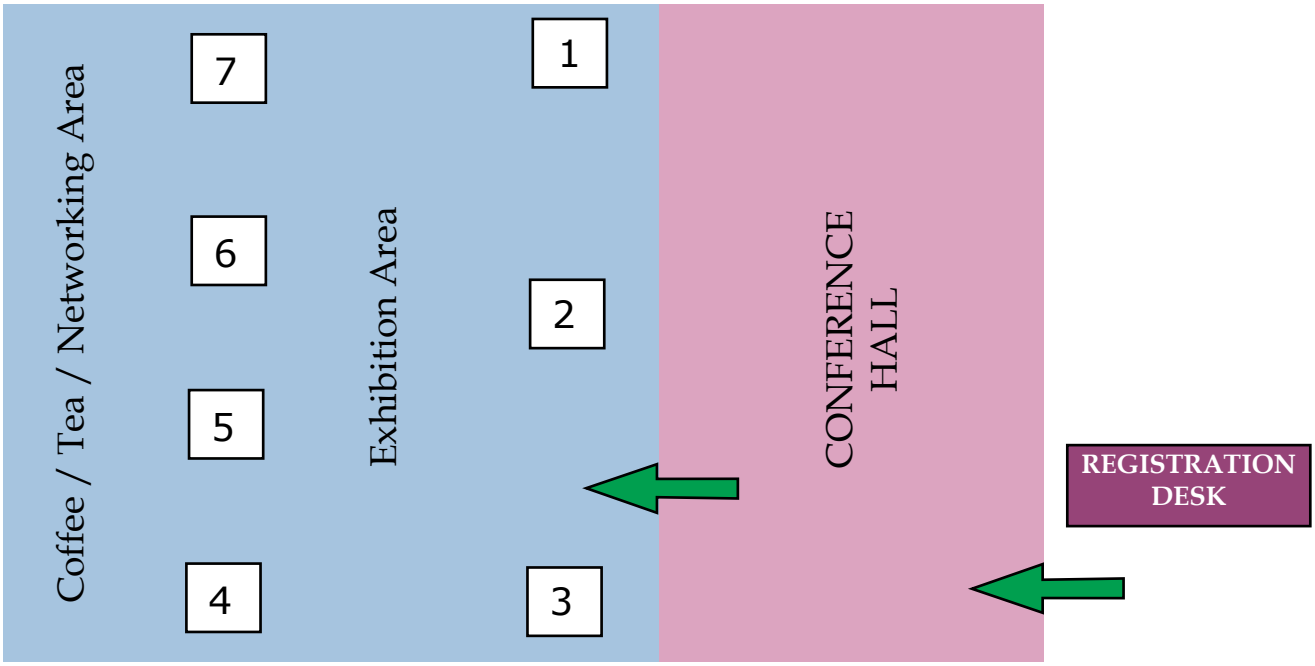
"It was a professionally managed event that was able to pull together a broad and relevant agenda presented by a well informed and insightful faculty. I would certainly be interested in attending future events organized by Virtue Insight"

Biosimilars and Proprietary Marketing Director, EMEA, Hospira, UK

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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"Well discussed topics with a distinguished and prolific panel of experts in their respective fields in Biosimilars"

Senior Business Analyst, Jakob & Partners

AGENDA AT A GLANCE

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

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Title Mr ☐ Mrs ☐ Ms ☐ Dr ☐

First Name

Surname

Company

Position

Address

Pincode

Telephone

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Email

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(Choose one of the following payment options)

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Standard Rate - £1150 + VAT per delegate (Valid From 29th January 2018)

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3 for 2 Offer

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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 + 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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