21st Pharmacovigilance 2020

"Latest developments in pharmacovigilance, drug safety and RMP"

26th & 27th February 2020
Pestana Chelsea Bridge Hotel
London, UK

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

NICHOLAS CALL
Special Agent
FDA

SHAANTANU DONDE
Senior Director, Medical Portfolio Development (Developed Markets), Upjohn UK

SUSAN WELSH
Chief Safety Officer
CSL Behring

G SCOTT CHANDLER
Global Head, Personalized Health Care (PHC) Safety, F. Hoffmann La Roche

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

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

JABEEN AHMAD
Global PV Consultant
Independent Consultancy

WIVINA DE WAELE
Director, Regional Safety Excellence EMEA.Global Drug Safety, Alexion

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency

RICARDA TIEMEYER
Associate Director Head of Pharmacovigilance
Biogen

RAJ BHOGAL
Head of Inspection, R&D Quality
Takeda

PHILIP OLUWOLE
Associate Principal Surveillance Specialist
Astrazeneca

MATE A. BALAZS
Country Head - Patient Safety – Hungary
Novartis

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring

SUMIT MUNJAL
Senior Medical Director, Head Europe PV
Takeda Pharmaceuticals

PHILLIP EICHORN
Senior Director (Worldwide Safety and Regulatory), Pfizer

JOHN POUSTIE
Medical Director & EU QPPV, Global PV
Norgine

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi Europe

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

LUIZ LIMA
Senior Global Patient Safety Physician Neurology, Ipsen

Organized by

Virtue Insight

Block 3, 86 Coombe Road
Croydon
CR0 5RA

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info.uk@virtueinsight.com

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"I found it to be very well structured, focused on topics of interest for every PV professional. All the speakers were amazing and I look forward attending your future conferences"

PhV Manager, Bausch Health

AGENDA AT A GLANCE

Key Speakers Include

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

MAGDA DAUDIN
Associate Director, Quality Assurance - PV Domain Expert, Janssen Pharmaceutical

KAREN CHENG
Safety Risk Lead
Pfizer

IVA SLAVCEVOVA
Deputy QP Pharmacovigilance/Global Patient Safety, Baxter

ANDREA OLIVA
Head of Pharmacovigilance
Mylan

NATALIE SPRINGVELD
Global Safety Leader
Bayer

TEA BABIC
Associate Director, Audits and Inspections, Global Pharmacovigilance Compliance, Teva

YVONNE NANCIU
Senior Manager PV & Medical Information, Local QPPV, Abbvie

MARJAN DZEPAROSKI
Head of Regulatory Affairs, Drug Safety & Intelectual Property, Bionika Pharmaceuticals

CHETAN SHATAPATHY
Principal Pharamcovigilance Physician - Oncology R&D Unit, AstraZeneca

BARBARA DE BERNARDI
Deputy EU QPPV and European Safety Office Head, Pfizer

NITHARNA SIVARAJAH
Pharmacovigilance Information Coordinator
MHRA

SALVATORE GIORGIO CICIRELLO
Senior Director Safety Science & PASS, Global Drug Safety & Risk Management, Celgene

NICOLE BAKER
Co-Founder
BioLogit

MADDALENA LINO
Safety Lead Director
Pfizer

MARY LYNNE VAN POELGEEST
President, World Federation for Incontinent Patients - (WFIP)

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

GEORGIA GAVRIILIDOU
Counsel
Sidley Austin

Plus many more COMING SOON.....

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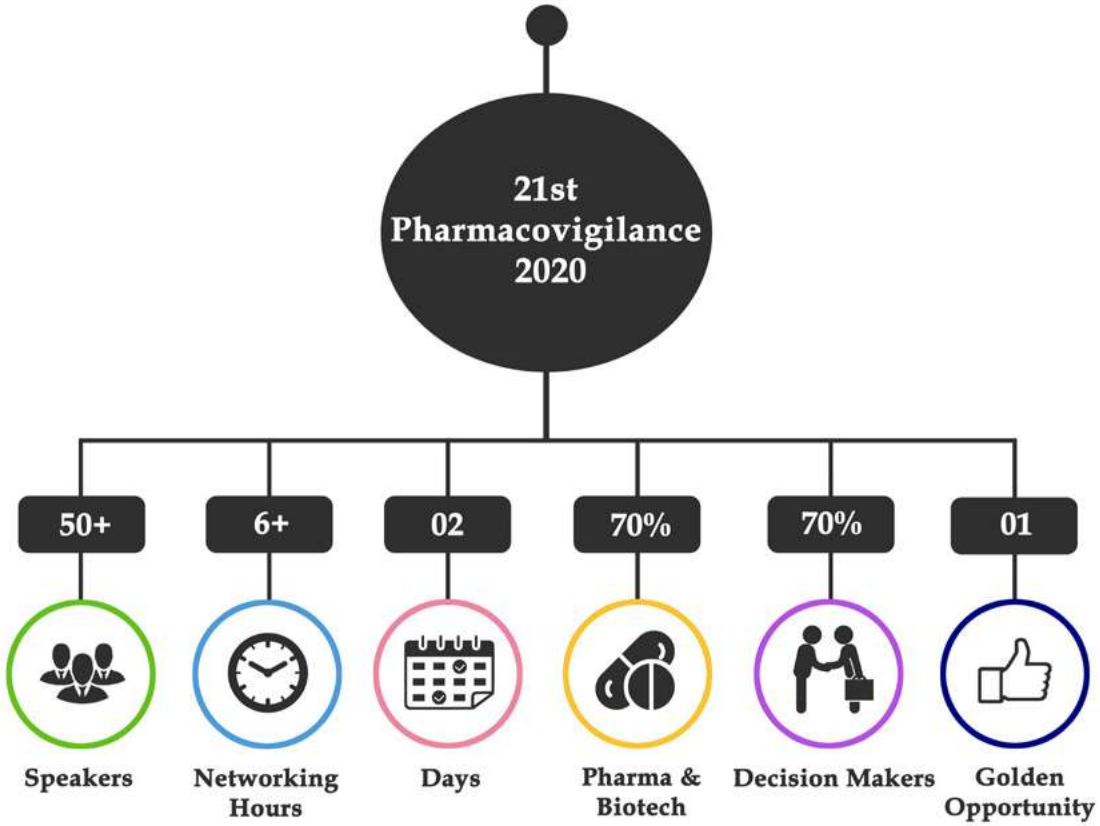
"Conference was very informative & added much knowledge about Pharmacovigilance systems, ADE, process flow of reporting, searching data & mobile networking"

Asst. Manager Regulatory Affairs, Emcure Pharmaceuticals

AGENDA AT A GLANCE

WHO ATTENDS?



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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

OUR HISTORY

Virtue Insight (VI) started it's wonderful journey in 2009 and now after a decade in the industry, we are honored to organise our 21st event in Pharmacovigilance to be held in 2020 in UK.

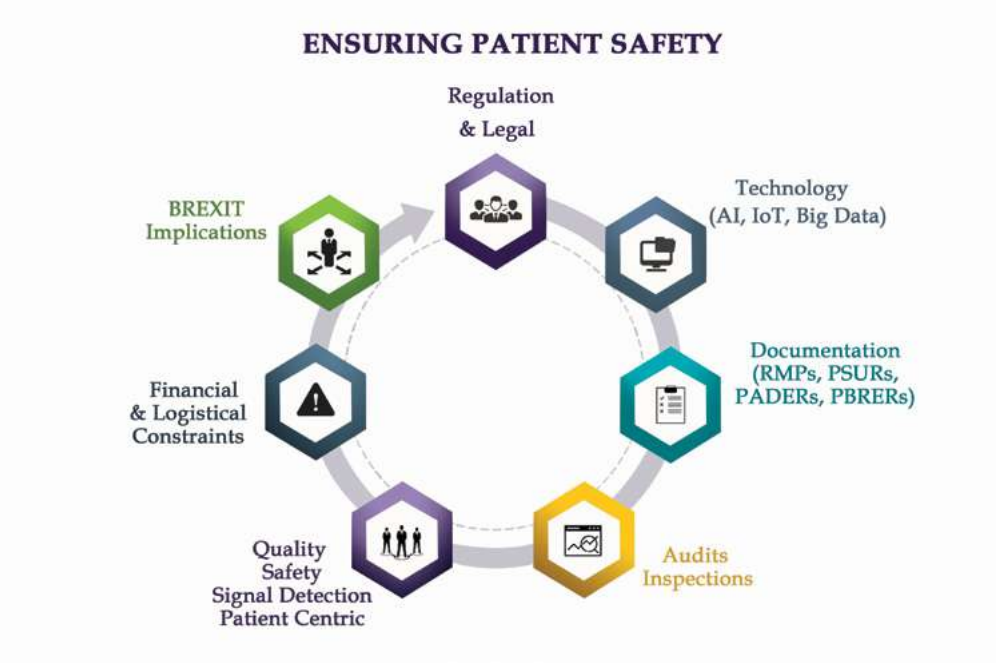
Over our past events, we have gained huge trust of our industry partners through our ability of providing best connect within the pharma regulators, stakeholders and the patients. Keeping our promise through all our 20 PV events in 3 different regions (UK, USA and India), our upcoming event holds the same intensity with newer challenges in PV along with new techniques to ease the process.

Our events have grown tremendously over the years within the pharma market, which lead to return of all our major clients every year to showcase their facilities to our senior level participants that help many to enhance their skills of critical drug safety evaluation process. We have been constantly rebuilding our content, format and agenda topics to stand ahead of what market demands.

This year, our event keeps an immersed eye on discussion of critical topics in PV domain, which capture influence of emerging technologies like AI, IoT, Big Data. Not merely that, we have exciting surprise activities which will help you to interact more with your peers. This will be surely an exciting event wherein you could get chance to meet big industry gems. Let's gather to shape the industry with your magnificent ideas.

UK is waiting for you!!!

MAJOR FOCUS ON



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, RMPs, PSURs, PADERs, PBRERs, Risk Management, Research & Development, Quality Assurance, Patient Safety, Signal Detection, Safety Surveillance, Outcomes Research, Data Analysis, Epidemiology, Medical Affairs, Regulatory Affairs & 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 - 26th February 2020

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

09:20 - Chairperson's opening remarks

SUSAN WELSH
Chief Safety Officer
CSL Behring

MARKET TRENDS & WAY FORWARD

09:30 – Harmonisation & Effective PV systems

IMPACT OF TECHNOLOGY

10:00 – 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

10:30 – Solution Provider Presentation

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

10:50 – Morning Coffee/Tea & Discussion

11:20 – 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
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Pharmacy practice and its guidelines
- Future Drivers for Pharmacovigilance
- New ways to generate evidence including real world evidence
- Proper communication - Sponsor – Site – CRO & Patients
- Best practices

Moderator:

JABEEN AHMAD
Global PV Consultant
Independent Consultancy

Panellists:

PHILLIP EICHORN
Senior Director (Worldwide Safety and Regulatory)
Pfizer

SUMIT MUNJAL
Senior Medical Director, Head Europe PV
Takeda Pharmaceuticals

PHILIP OLUWOLE
Associate Principal Surveillance Specialist
Astrazeneca

NITHARNA SIVARAJAH
Pharmacovigilance Information Coordinator
MHRA

12:00 – Solution Provider Presentation

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12:20 – Networking luncheon

13:20 - Regulation of PV in non-EU Countries

- Regulatory requirements in the region: Macedonia, Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo
- In-depth look at pharmacovigilance compliance with country specific environments

MARJAN DZEPAROSKI
Head of Regulatory Affairs, Drug Safety & Intelectual Property, Bionika Pharmaceuticals

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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 - 26th February 2020

QUALITY - SAFETY – SIGNAL DETECTION

13:40 – Panel Discussion – Quality, Safety & Signal Detection - Future of 2020

- Strategies for best practice in Signal Detection
- Exploring patient support and marketing research programs from a safety perspective
- 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

Panellists:

JOHN POUSTIE
Medical Director & EU QPPV, Global Pharmacovigilance
Norgine

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring

YVONNE NANCIU
Senior Manager PV & Medical Information, Local QPPV
Abbvie

MADDALENA LINO
Safety Lead Director
Pfizer

14:20 – Drug Safety contributions to First-In-Human (FIH) studies:

- Supporting translation of safety data from preclinical to clinical
- Evaluating possible safety concerns
- Identifying potential risks, designing appropriate risk minimization measures

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring

14:50 – EU-RMP

- Changing paradigms for the list of safety concerns
- Transferring from previous templates to the R(2) template
- Reclassification of risks as not important for inclusions in the EU-RMP

KAREN CHENG
Safety Risk Lead
Pfizer

15:20 – Afternoon Tea/Coffee

15:40 - Emerging PV technologies and the future of the Drug Safety Professional: practical considerations for adoption of machine learning and NLP

- A framework model for leveraging PV innovation
- Development of cognitive services and the role of drug safety professional
- How the PV tech revolution will affect role of the drug safety professional
- How to pave the way to transformation and role evolution

SALVATORE GIORGIO CICIRELLO
Senior Director Safety Science & PASS, Global Drug Safety & Risk Management, Celgene

16:10 – Brexit Implications for the UK – Impacts on PV

- What would 'no deal' mean for medicine?
- Time to prepare now with not much of choice
- Solving stocked drugs issue
- Preparing for a smooth transition
- Pitfall and Learnings
- Innovation in PV

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring

Panellists:

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"A great platform to understand the current practices & situation all across the industry, as well as individual approach of each company toward the goal of patient safety. "

Senior Executive, Lupin

AGENDA AT A GLANCE

DAY ONE - 26th February 2020

CHETAN SHATAPATHY
Principal Pharamcovigilance Physician - Oncology R&D Unit, AstraZeneca

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi Europe

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

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 - 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 - 27th February 2019

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

09:20 – Chairperson opening remarks

SUSAN WELSH
Chief Safety Officer
CSL Behring

PV FOR 2020

09:30 – PV auditing: Innovation to stay ahead in our evolving regulatory and business landscape

- PV Audit methodologies & alternative approaches
- Audit scope and entities in an agile and ever changing business context
- Technology and big data driving Automation from risk based planning to audit reporting

MAGDA DAUDIN
Associate Director, Quality Assurance - Pharmacovigilance Domain Expert, Janssen Pharmaceutical Companies of Johnson & Johnson

10:00 – Overview of FDA OCI and our involvement in Clinical Fraud

NICHOLAS CALL
Special Agent
FDA

10:30 – Solution Provider Presentation

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10:50 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:10 – Keynote Panel Discussion: Pharmacovigilance and Patient Safety

- Driving patient centricity into your PV plans
- Pharmacovigilance as a tool for safety and monitoring
- Patient-Perspectives in Benefit-Risk Assessments
- 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

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring

Panellists:

SHAANTANU DONDE
Senior Director, Medical Portfolio Development (Developed Markets), Upjohn UK

MATE A. BALAZS
Country Head - Patient Safety – Hungary
Novartis

RICARDA TIEMEYER
Associate Director Head of Pharmacovigilance
Biogen

MARY LYNNE VAN POELGEEST
President
World Federation for Incontinent Patients - (WFIP)

11:50 – Communication between global and local affiliate during HA Pharmacovigilance inspection

- Identify "best common practice" to be prepared for a PV Inspection: after receiving a communication by HA about a pharmacovigilance inspection, global and local function has to prepare and verify that everything will be ok during the inspection.
- List of aspects that's important to remember
- How local and global communicate during a PV inspection: during an inspection to an affiliate it's very important the continuous updating from local to global, in order to be aware about any potential finding and to be supportive to the affiliate for any question; so, how this communication can be ensured?

ANDREA OLIVA
Head of Pharmacovigilance
Mylan

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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

DAY TWO - 27th February 2019

12:20 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:20 – Panel Discussion – PV – Risk Management and Planning

- Risk management in the lifecycle of a drug
- How effective is your risk management?
- Challenges and overcoming problems in Pharmaceutical product life cycle management
- Implementation and maintenance of RMP's – Overcoming its challenges
- Risk management in different jurisdictions
- Benefit/Risk ratio: the common denominator
- New approaches for managing benefit-risk
- Research and development improvement

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring

Panellists:

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

BARBARA DE BERNARDI
Deputy EU QPPV and European Safety Office Head
Pfizer

IVA SLAVCEVOVA
Deputy QP Pharmacovigilance/Global Patient Safety
Baxter

NICOLE BAKER
Co-Founder
BioLogit

LUIZ LIMA
Senior Global Patient Safety Physician Neurology,
Ipsen

14:00 – Patient-centric Safety: Innovative approaches and novel methodologies

- Emerging role of genetics in understanding drivers of toxicity
- Translating biology into clinical decision-making
- Applying advanced technologies to perform novel safety analyses

G SCOTT CHANDLER
Global Head, Personalized Health Care (PHC) Safety
F. Hoffmann La Roche

14:30 – 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?

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency

15:10 - Afternoon Tea/Coffee

DATA COLLECTION – MANAGEMENT

15:30 – Panel Discussion - 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

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring

Panellists:

WIVINA DE WAELE
Director, Regional Safety Excellence EMEA.Global Drug Safety, Alexion

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

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Safety Physician, Sciformix

DAY TWO - 27th February 2019

NATALIE SPRINGVELD
Global Safety Leader
Bayer

TEA BABIC
Associate Director, Audits and Inspections, Global Pharmacovigilance Compliance, Teva

REGULATION OVERVIEW & UPDATE

16:10 – 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

Panellists:

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

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

RAJ BHOGAL
Head of Inspection, R&D Quality
Takeda

GEORGIA GAVRIILIDOU
Counsel
Sidley Austin

MARJAN DZEPAROSKI
Head of Regulatory Affairs, Drug Safety & Intelectual Property, Bionika Pharmaceuticals

16:50 - 17:00 – 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 - sponsor.uk@virtueinsight.com

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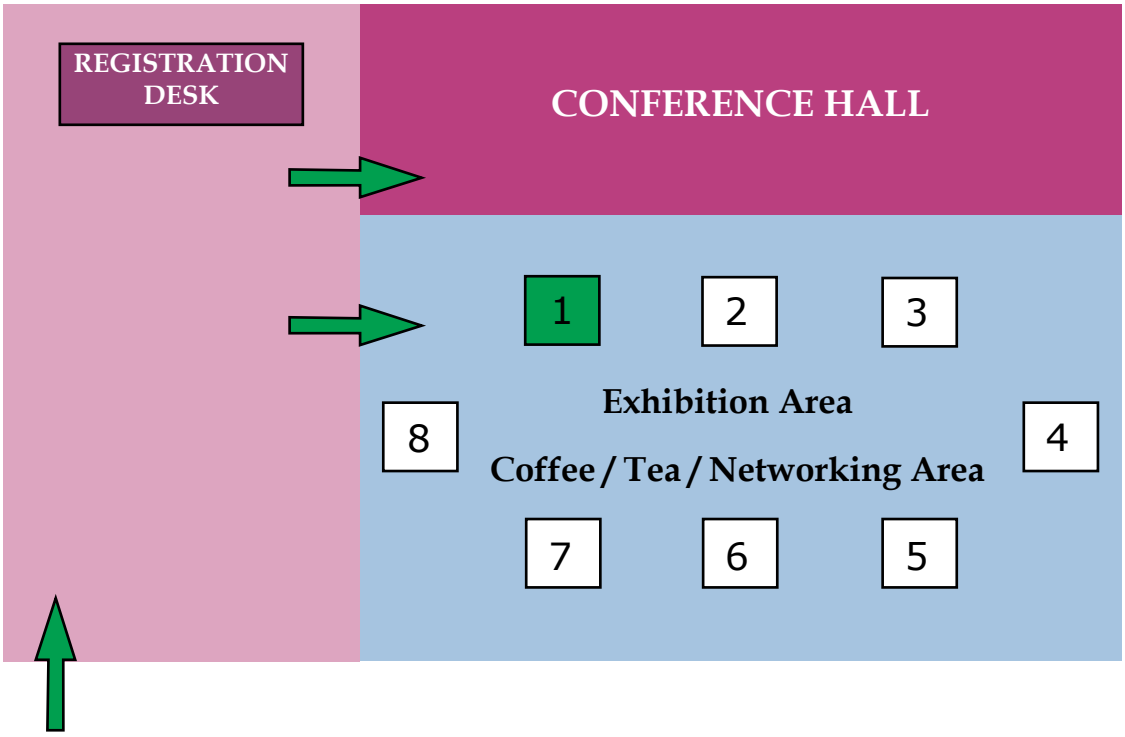
"This conference was very good for the pharmacovigilance professionals as well as business people. Organising this event and the event management was nicely done by Virtue Insight"

IT Administrator, Oviya Med Safe Pvt. Ltd

AGENDA AT A GLANCE

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



1	COVANCE	**4**		**7**	
2		**5**		**8**	
3		**6**			

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

REGISTER ONLINE :

Link : https://www.virtueinsight.com/pharma/21st-Pharmacovigilance-2020/products/

For Multiple Bookings - Photocopy this form and send it to **info.uk@virtueinsight.com**

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Surname

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Position

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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 vendors 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 no extra cost.

Presentation: If you cannot attend the conference, you can still purchase the presentations for £500.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will 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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