

"Latest developments in pharmacovigilance, drug safety & risk management"

24th & 25th Feb 2021, Virtual Conference - TimeZone - GMT



Key Speakers Include



WILLIAM WANG Executive Director, Clinical Safety Statistics Merck (USA)



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



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



KHAUDEJA BANO
Executive Medical Director, Combination
Product Safety Head, Amgen (USA)



SUMIT MUNJAL Vice President, Global Patient Safety Evaluation, Takeda



JOHN SOLOMON Head of Pharmacovigilance - UK & Ireland Sanofi



OYINKANSOLA ODEBO Assistant Director, Drug Safety Clinical Research, Supernus Pharmaceuticals (USA)



ALESSANDRO VAGHEGGINI Associate Principal Biostatistician, Clinical Safety Statistics MSD (CH)



TEA BABICAssoc. Dir - Audits and Inspections
Teva



DAVID J LEWIS EU QPPV Head QPPV Office Novartis



SHAUN COMFORT
Principal Scientific Enablement Director
Roche - Genentech



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



DAVID JEFFERYS Sr. VP Regulatory Eisai



VALENTINA MANCINI Director PV, EU QPPV Shionogi Europe



ROSALINA DOMIN
Senior Director, QA and Deviation
Management Head, PV Quality, Sanofi



RAJ BHOGAL Sr. Director, R&D Audits & Inspections Jazz Pharmaceuticals



ANDREA OLIVA Head of Pharmacovigilance Viatris



JAYLAXMI NALAWADE Associate Director - Pharmacovigilance & REMS, Lupin



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



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





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Key Speakers Include



RUDI SCHEERLINCK Global Head Pharmacovigilance Risk Management, Nestle



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



JOHN POUSTIE Senior Director, Global Pharmacovigilance Norgine



SUE REES
Pharmacovigilance Expert, (Former EU QPPV
Executive Director, Global Safety, Amgen)



GAURI UTTURKAR Senior Manager - Pharmacovigilance Glenmark Pharmaceuticals



LISBETH TOFTE HEMMINGSEN Director, Drug Safety Consult



NICOLE BAKER Co-Founder BioLogit



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

Plus more COMING SOON.....

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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 - info.uk@virtueinsight.com







#VIphv

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OUR HISTORY

After the successful journey of a series of 23 Pharmacovigilance conferences, Virtue Insight is proud to announce its **24th Pharmacovigilance 2021**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade**. Considering the current pandemic situation, for the 2021st edition, the agenda includes a host of new and exciting features. Take a chance and make it count by attending this conference to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

The global pharmacovigilance market size was estimated at USD 4.87 billion in 2019 is expected to increase at a compound annual growth rate (CAGR) of 13.2% from 2020 to 2027. An increase in the prevalence of chronic diseases has led to an increase in drug consumption worldwide. Thereby demand for new drug development via extensive clinical trials has increased.

This event will bring together top pharmaceutical, biotechnology and regulatory representatives under one roof that will address the key issues of the industry. 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.

It gives me great pleasure in welcoming all of you to the Virtue Insight's **24th Pharmacovigilance 2021**. I wish and pray that all our efforts will be beneficial to our industries and to our all at large.



E-Certificate of attendance would be provided to attendees on request, upon completion of conference

FOCUSES ON

- · Overcoming this Pandemic Issues Drug Safety Strategy for Pharmaceutical organisations
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Key factors driving the current global Pharmacovigilance (PV) market?
- Pharmacovigilance and assessment of drug safety reports during COVID 19
- What are the market opportunities, market risk and market overview of the (PV) market?
- PV Audit & Inspections Keeping on the right side of Inspectors
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Practical approaches Quality, Safety & Signal Detection
- Medical devices Increasing safety perspective
- · Improving patient safety
- New Technologies in Pharmacovigilance (AI/ Machine Learning, IoT)
- Brexit Implications for the Pharmaceutical (pharmacovigilance) Industry
- RoW Recent developments and future perspectives
- The developing regulatory framework in advanced and developing markets EU, USA & ROW
- Be part of a major networking opportunity

WHO SHOULD ATTEND

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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DAY ONE - 24th February 2021



13:50 - Panel Discussion - PV - Regulatory Updates

- Impact of the pandemic
- Key current changes and their impact on current PV
- Impact of Brexit Regulatory aspect
- Future Legislation: Pharmacovigilance Industry
- PV System Legislation Updates

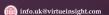


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11:30 - Keynote Panel Discussion: Improvising the PV

11:10 - Morning Coffee/Tea & Discussion

ecosystem for betterment





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DAY ONE - 24th February 2021

- Outsourcing Key areas to look out while outsourcing
- Enhancing communication between regulators, regional authorities and patients

Moderator:

Panellists:

DAVID JEFFERYS

Sr. VP Regulatory

Eisai

MICHAEL BEAN

Senior Director, Regulatory Compliance R&D Johnson & Johnson

YUUNG YUUNG YAP

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

14:40 - Drug Safety and Pharmacovigilance processes: Ensuring a smooth and accurate workflow

OYINKANSOLA ODEBO

Assistant Director, Drug Safety Clinical Research Supernus Pharmaceuticals (USA)

15:10 - Afternoon Tea/Coffee

15:30 - How to ensure quality of PV deliverables

- · What quality checks are really needed?
- Key Metrics and KPIs
- Proactive Quality Management
- Relationship with PV stakeholders

ROSALINA DOMIN

Senior Director, QA and Deviation Management Head, PV Quality, Sanofi

DATA COLLECTION - MANAGEMENT

16:00 - Panel Discussion - PV Audit & Inspections - Keeping on the right side of Inspectors

- Key international legislation and guidelines covering PV Quality Management, including PV audits and PV in spections
- Creating and maintaining a risk based PV audit algorithm – and a corresponding audit program
- Design and implement appropriate and effective corrective and preventive actions
- Always prepared for a regulatory PV inspection
- Data management is a key principle of pharmacovigilance
- Risk based selection criteria for auditing
- Relationship to other GxPs

Moderator:

VALENTINA MANCINI Director PV, EU QPPV Shionogi Europe

Panellists:

TEA BABIC

Assoc. Dir - Audits and Inspections Teva

RAJ BHOGAL

Senior Director, R&D Audits & Inspections Jazz Pharmaceuticals

JAYLAXMI NALAWADE

Associate Director - Pharmacovigilance & REMS Lupin

FRANCK SCHWARTZ

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

LISBETH TOFTE HEMMINGSEN

Director, Drug Safety Consult

16:50 - End of the conference









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AGENDA AT A GLANCE

DAY TWO - 25th February 2021

IMPACT OF TECHNOLOGY

09:40 - Future Pharmacovigilance Systems: Adoption of emerging technologies

- 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

10:20 - Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration

IOHN POUSTIE

Senior Director, Global Pharmacovigilance Norgine

10:50 - Solution Provider Presentation

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11:10 - Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:30 - Keynote Panel Discussion : Patient Centric - Pharmacovigilance & Patient Safety

- Driving patient centricity into your PV plans
- Challenges for safety reporting activities due to the COVID-19 pandemic
- Pharmacovigilance as a tool for safety and monitoring
- Pharmacovigilance and assessment of drug safety reports during COVID 19
- Patient-Perspectives in Benefit-Risk Assessments
- Adapting operations to changing conditions
- Leveraging technology to transform patient safety
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

Panellists:

WIVINA DE WAELE

Director, Regional Safety Excellence EMEA.Global Drug Safety, Alexion Pharmaceuticals

MARY LYNNE VAN POELGEEST

President

World Federation for Incontinent Patients - (WFIP)

SUE REES

Pharmacovigilance Expert, (Former EU QPPV Executive Director, Global Safety, Amgen)

NICOLE BAKER

Co-Founder BioLogit

12:20 - Solution Provider Presentation

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12:40 - Networking luncheon

RISK MANAGEMENT & PLANNING

13:50 - Panel Discussion - PV - Risk Management & Planning

- Global approach to good pharmacovigilance and risk management
- · Risk management in the lifecycle of a drug
- How effective is your risk management?
- Implementation and maintenance of RMP's Overcoming its challenges
- Risk management in different jurisdictions
- Benefit/Risk ratio: the common denominator
- Research and development improvement

Moderator:

Panellists:

GAURI UTTURKAR

Senior Manager - Pharmacovigilance Glenmark Pharmaceuticals









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DAY TWO - 25th February 2021

CHETAN SHATAPATHY

Principal Pharamcovigilance Physician - Oncology R&D Unit, AstraZeneca

RUDI SCHEERLINCK

Global Head Pharmacovigilance Risk Management Nestle

QUALITY - SAFETY - SIGNAL DETECTION

14:40 - A PV Organization's Transformational Journey **Towards Combination Product Safety**

- Discuss the changing environment of post marketing safety and factors driving the change
- Key challenges and recommended best practices for the PV organizational transformation
- How has the role of PV and the definition of Safety and Risk evolved to support Combination product safety

KHAUDEJA BANO

Executive Medical Director, Combination Product Safety Head, Amgen (USA)

15:20 - Afternoon Tea/Coffee

15:40 - Safety Evaluation in Master Protocols

- Aggregate safety assessment planning and monitoring
- Statistical considerations in multi-cohort and multi-arm
- Safety evaluation with statistical multiplicity considerations

WILLIAM WANG

Executive Director Merck (USA)

ALESSANDRO VAGHEGGINI

Associate Principal Biostatistician, Clinical Safety Statistics, MSD (CH)

16:20 - How Good Are You? Documenting and Analyzing Human Causality Performance in PV

• How to perform comparative analysis of causality assessments of Drug-Event-Pairs

- Common metrics and results for Human Expert causality assessments from the medical literature
- Future directions simple steps to improving causality assessments

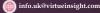
SHAUN COMFORT

Principal Scientific Enablement Director Roche - Genentech

16:50 - End of the conference









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AGENDA AT A GLANCE

REGISTER ONLINE:

Link: https://www.virtueinsight.com/pharma/24th-Pharmacovigilance-2021--Virtual-Conference/products/

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

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B Delegates @ £1000 +VAT (Valid Till 28th January 2021) STANDARD RATE		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
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