

31st Pharmacovigilance 2023

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

01st & 02nd February 2023, Radisson RED London Heathrow, UK

AGENDA AT A GLANCE

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

Key Speakers Include



KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen



TARAK THAKKER
Director, Safety Systems
BeiGene (USA)



SIDDHARTH CHACHAD
Executive Vice President & Head - Global
Clinical Management, Dr. Reddy's Laboratories



ELIAN KHAZNEH
Head of Global Patient Safety Benefit Risk
Strategy & Mgmt, Merck Healthcare



JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi



FABIO DE GREGORIO
Vice President, Head of Drug Safety Europe
Shionogi Europe



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



RAJ BHOGAL
Senior Director, R&D Audits & Inspections
Jazz Pharmaceuticals



SUMIT MUNJAL
Vice President, Global Patient Safety
Evaluation, Takeda Pharmaceuticals



FATIMA YOUSEF GHETHAN
Quality Culture & Implementation Manager,
Executive Administration of Quality & Patient
Safety, Makkah Healthcare Cluster (UAE)



YVONNE NANCIU
Country Head Pharmacovigilance
Bayer



LUIZ LIMA
Senior Medical Director
Ipsen



ADI MEISTER
PV Sr. Manager
Teva



ANNA HELENA STAHL
Senior Director, Pharmacovigilance; EU QPPV
Bavarian Nordic



ROBERT MASSOUH
Director - Risk Management Product Lead
Pfizer



ALINA TUDOR
Senior Director, Pharmacovigilance
Kyowa Kirin International



HUMAIRA QURESHI
CEO
Qinecsa Solutions



ROHAN MANE
Director, Safety Risk Management Centre of
Excellence, Pfizer



RISHI CHOPRA
Global Head of Pharmacovigilance Regions
CSL Behring



ANDREA OLIVA
Head of Pharmacovigilance
Viartis



PAV RISHIRAJ
Director - Pharmacovigilance & ABPI PV
Expert Chair, Ipsen



DNYANESHWAR SANAP
EU/UK QPPV, Head Regional PV and Global
Compliance & Training
Glenmark Pharmaceuticals

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Director PV, EU QPPV
Shionogi Europe



ATTILA OLAH
Head of Global Patient Safety
Gedeon Richter



TEA BABIC
Director, Head of Global PV Audits and
Inspections, Deputy Head PV Compliance
Teva



DANIELA DI COSMO
Senior PV Manager, Global PV
Ferring Pharmaceuticals



GRAEME LADDS
CEO
PharSafer



DARIUS-JEAN NAMDJOU
Head of Regulatory Affairs &
Pharmacovigilance, Immunic Therapeutics



DEEPA ARORA
Chief Executive Officer
CLINEXEL Life Sciences



GAURI UTTURKAR
Patient Safety Physician
UCB



MIJAL CHAVDA
Global Head of GxP Inspection & GVP Quality
Kyowa Kirin



OLEKSANDR KARPENKO
Director
Olexacon



ALESSANDRO VAGHEGINI
Associate Principal Biostatistician, BARDS-CSS
MSD Merck Sharp & Dohme



MARIA BEATRICE PANICO
Principal Consultant
Scendea



LUDIVINE DOUARIN
Benefit-Risk Expert
Sanofi



MARINA SUVAKOV
Global Head Product Safety Surveillance
Philip Morris International



TOMMASO VENTURI
Corporate Pharmacovigilance Risk Assessment
Specialist, ITALFARMACO



DIMITRIS ZAMPATIS
Global Program Safety Lead
Sandoz



EMANUEL LOHRMANN
Lead Safety Physician
Otsuka Pharmaceutical



ALEXANDER ROUSSANOV
International Partner, Life Sciences and Privacy
Arnold & Porter



KAPIL BHUTADA
Director, Pharmacovigilance Compliance and
Training, Medicago

Plus More Coming Soon...



KETAN MARULKAR
Senior Pharmacovigilance Officer
Chanelle Pharma

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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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KEY THEMES DISCUSSED:

- Future of pharmacovigilance - Making medicines safe in an increasingly complex world
- Market analysis - Pharmacovigilance in 2023 - future horizons and efficiencies
- Refining the PV environment - Rising back from the pandemic
- Rethinking relationship between Sponsor, Site, CRO & Patients - Working together
- Why does pharmacovigilance sometimes fail and where could the fault lie?
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Quality, Safety & Signal Detection - Overall approach
- From policy to practice: Prioritising Patients
- Developmental Risk management plans in Pharmacovigilance
- Impact of technology - Automation in Pharmacovigilance: A Closer look at use cases
- Plan, develop and implement the PV Audit strategy plan
- Medical devices - Increasing safety perspective
- Case studies from various countries on the PV frameworks around the world
- Prioritising Patients - Reshaping patient safety
- Brexit Implications for the Pharmaceutical (pharmacovigilance) Industry
- New Technologies in Pharmacovigilance (AI/ Machine Learning, IoT)
- Regulatory - EU and UK Regulations & Guidelines in Pharmacovigilance
- Be part of a major networking opportunity

OUR HISTORY:

After the successful journey of a series of 30 Pharmacovigilance conferences, Virtue Insight is proud to announce its 31st Pharmacovigilance 2023. We have been delivering the conference through close collaboration with the industry leaders for more than a decade. For the 2023 edition, the agenda includes a host of new and exciting features focusing on how the industry should evolve especially after the pandemic. Take a chance and make it count by attending our event to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

As per current market situation, the global pharmacovigilance market was approximately USD 6.97 billion in 2021 and is expected to generate around USD 8.33 billion by 2025, at a CAGR of around 11.6% between 2019 and 2025. The global pharmacovigilance market size is expected to reach USD 15.84 Billion by 2030 according to a new study. 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 31st Pharmacovigilance 2023. I wish and pray that all our efforts will be beneficial to our industries and to our all at large.

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 - 01st February 2023

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

09:30 – Chairperson opening remarks

OLEKSANDR KARPENKO
Director
Olexacon

MARKET TRENDS & WAY FORWARD

09:40 – Models for an International Pharmacovigilance function

In industry two main models for Pharmacovigilance in the affiliate space exist. This presentation looks to describe those models and describes the change management process when adapting from one model to another.

RISHI CHOPRA
Global Head of Pharmacovigilance Regions
CSL Behring

10:20 – BeiGene's journey on standardizing Clinical Trials and how it enables automated intake of SAEs

TARAK THAKKER
Director, Safety Systems
BeiGene (USA)

10:50 – Morning Coffee / Tea & Networking

CHALLENGES & OPPORTUNITIES

11:20 – Keynote Panel Discussion: Refining the PV environment - Rising back from the pandemic

- Brexit and its effect on Pharmacovigilance in the EU
- Lessons learnt from the pandemic
- Staying ahead in the race - Current trends for PV, and new and future guidelines
- Outsourcing in Pharmacovigilance - Best Practices, Challenges and key consideration
- Best practices & the way forward

Moderator:

DEEPA ARORA
Chief Executive Officer
CLINEXEL Life Sciences

Panellists:

FABIO DE GREGORIO
Vice President, Head of Drug Safety Europe
Shionogi Europe

YVONNE NANCIU
Country Head Pharmacovigilance
Bayer

RISHI CHOPRA
Global Head of Pharmacovigilance Regions
CSL Behring

ATTILA OLAH
Head of Global Patient Safety
Gedeon Richter

DANIELA DI COSMO
Senior PV Manager, Global PV
Ferring Pharmaceuticals

12:10 – Topic TBC

HUMAIRA QURESHI
CEO
Qinesca Solutions

12:40 – Networking luncheon

QUALITY - SAFETY - SIGNAL DETECTION

13:40 – Panel Discussion – Quality, Safety & Signal Detection – Overall approach

- Traditional and innovative approaches for signal detection
- Hybrid method to produce precise results and improve patient safety
- Developing a global safety intelligence process
- Quality assurance and compliance
- Exploring patient support and marketing research programs from a safety perspective
- Latest updates and hot topics

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OLEKSANDR KARPENKO
Director
Olexacon

Panellists:

FATIMA YOUSEF GHETHAN
Quality Culture & Implementation Manager, Executive
Administration of Quality & Patient Safety
Makkah Healthcare Cluster (UAE)

ANNA HELENA STAHL
Senior Director, Pharmacovigilance; EU QPPV
Bavarian Nordic

ALESSANDRO VAGHEGGINI
Associate Principal Biostatistician, BARDS-CSS
MSD Merck Sharp & Dohme

MARINA SUVAKOV
Global Head Product Safety Surveillance
Philip Morris International

EMANUEL LOHRMANN
Lead Safety Physician
Otsuka Pharmaceutical

14:30 - Patient centricity and Benefit - Risk

In context of Benefit-Risk assessment patient experience data can be used for

- Assessing patients preferences and trade-offs for BR
- Identification of patient needs and relevant endpoints for patients
- Understanding impact of risks on patients and tolerability

LUDIVINE DOUARIN
Benefit-Risk Expert
Sanofi

15:00 - Application of a probabilistic algorithm in signal management

- Validation of the algorithm
- Use in signal detection
- Use in signal validation

FABIO DE GREGORIO

Vice President, Head of Drug Safety Europe
Shionogi Europe

15:30 - Afternoon Tea / Coffee

15:50- Case Processing - The Most Important Part of Pharmacovigilance?

- Reviewing the current industry landscape for clinical and post marketing drug safety
- Identifying and highlighting of key issues Companies face and how this influences safety data capture and processing
- Exploring how AI & Automation can provide a complete solution

GRAEME LADDS
CEO
PharSafer

16:10 - Patient Safety & Risk Management Excellence For pharmacovigilance and drug safety

- What is the impact of using the risk management tool for PV and medication safety excellence
- What is the impact of using the patient safety tool for PV and medication safety excellence
- Pharmacovigilance and medication safety excellence

FATIMA YOUSEF GHETHAN
Quality Culture & Implementation Manager, Executive
Administration of Quality & Patient Safety
Makkah Healthcare Cluster (UAE)

SPONSOR - SITE - CRO - PATIENTS

16:30 - Panel Discussion - Rethinking relationship between Sponsor - Site - CRO & Patients - Working together for safety

- Proper communication between - Sponsor - Site - CRO & Patients
- Best Practices in Pre-Screening before selecting your partner
- How can you maximize the effectiveness of your partnership?

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- Working together to improve drug safety
- Patients involvement for a better PV knowledge - Patient support programs
- Mistakes that will doom a CRO-Sponsor partnership

Moderator:

OLEKSANDR KARPENKO

Director

Olexacon

Panellists:

SIDDHARTH CHACHAD

Executive Vice President & Head - Global Clinical Management, **Dr. Reddy's Laboratories**

SUMIT MUNJAL

Vice President, Global Patient Safety Evaluation

Takeda Pharmaceuticals

DIMITRIS ZAMPATIS

Global Program Safety Lead

Sandoz

KETAN MARULKAR

Senior Pharmacovigilance Officer

Chanelle Pharma

.....

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

.....

17:20 - 18:20 - Networking Drinks Session

.....

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DAY TWO - 2nd February 2023

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

09:30 – Chairperson opening remarks

OLEKSANDR KARPENKO
Director
Olexacon

PV FOR FUTURE

09:40 – Demystifying device / product malfunction for PV

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

10:20 – A cross functional approach for benefit risk strategy, management, and documentation

- Benefit Risk Strategy Document as a solution for core benefit risk and safety planning throughout the lifecycle
- Process for the creation and management of these documents

ELIAN KHAZNEH
Head of Global Patient Safety Benefit Risk Strategy & Mgmt
Merck Healthcare

10:50 – Morning Coffee / Tea & Discussion

PATIENT SAFETY

11:10 – Keynote Panel Discussion: From policy to practice: Prioritising Patients

- Driving patient centricity into your PV plans
- Developing a prioritisation framework for patients
- Patient-Perspectives in benefit-risk assessments
- A review of general issues and the specific challenges with patients
- Reshaping patient safety - Next generation pharmacovigilance for enhanced patient safety

Moderator:

YVONNE NANCIU
Country Head Pharmacovigilance
Bayer

Panellists:

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

ADI MEISTER
PV Sr. Manager
Teva

LUIZ LIMA
Senior Medical Director
Ipsen

ROHAN MANE
Director, Safety Risk Management Centre of Excellence
Pfizer

12:10 – Solution Provider Presentation

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12:40 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:40 – Panel Discussion – Developmental risk management plans in Pharmacovigilance

- Impact of changing regulations and the dynamic nature of European RMP for safety concerns
- Guidance on risk management plans
- Managing risks / Adminstrating risks – Right way in handling situations
- Tailored approaches towards benefit-risk evaluations
- Risk management in different jurisdictions
- New approaches to managing benefit-risk

Moderator:

ALINA TUDOR
Senior Director, Pharmacovigilance
Kyowa Kirin International

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Panellists:

ROBERT MASSOUH

Director - Risk Management Product Lead
Pfizer

DNYANESHWAR SANAP

EU/UK QPPV, Head Regional PV and Global Compliance & Training, Glenmark Pharmaceuticals

TOMMASO VENTURI

Corporate Pharmacovigilance Risk Assessment Specialist
ITALFARMACO

KAPIL BHUTADA

Director, Pharmacovigilance Compliance and Training
Medicago

GAURI UTTURKAR

Patient Safety Physician
UCB

IMPACT OF TECHNOLOGY

14:30 - Artificial Intelligence (AI) tools and pharmacovigilance

- Improving coding of adverse events via AI
- Natural language processing for case narrative review
- AI algorithms for signal detection
- AI and biobanks

MARIA BEATRICE PANICO

Principal Consultant
Scendea

14:50 - Afternoon Tea / Coffee

AUDITS & INSPECTIONS

15:10 - Panel Discussion - Plan, develop and implement the PV Audit strategy plan

- PV Inspection readiness: What to expect? How ready can we be?
- PV Inspection Readiness from inspector perspective
- PV Audit Readiness from auditor perspective
- Methodologies, scope and oversight

Moderator:

MIJAL CHAVDA

Global Head of GxP Inspection & GVP Quality
Kyowa Kirin

Panellists:

RAJ BHOGAL

Senior Director, R&D Audits & Inspections
Jazz Pharmaceuticals

VALENTINA MANCINI

Director PV, EU QPPV
Shionogi Europe

TEA BABIC

Director, Head of Global PV Audits and Inspections, Deputy Head PV Compliance
Teva

ANDREA OLIVA

Head of Pharmacovigilance
Viatris

KAPIL BHUTADA

Director, Pharmacovigilance Compliance and Training
Medicago

REGULATION OVERVIEW & UPDATE

16:00 - Panel Discussion: Regulatory - EU and UK Regulations & Guidelines in Pharmacovigilance

- PV System Legislation Updates
- Key current changes and their impact on current PV
- Brexit - Regulatory aspect
- Outsourcing concepts and regulation implementation
- Future Legislation: Pharmacovigilance - Industry Vision
- Enhancing communication between regulators, regional authorities and patients

Moderator:

PAV RISHIRAJ

Director - Pharmacovigilance & ABPI PV Expert Chair
Ipsen

Panellists:

MICHAEL BEAN

Senior Director, Regulatory Compliance R&D
Johnson & Johnson

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DAY TWO - 2nd February 2023

DARIUS-JEAN NAMDJOU

Head of Regulatory Affairs & Pharmacovigilance
Immunix Therapeutics

MARIA BEATRICE PANICO

Principal Consultant
Scendea

ALEXANDER ROUSSANOV

International Partner, Life Sciences and Privacy
Arnold & Porter

.....
16:50 - 17:00 – Chairperson's closing remarks and end of the
conference
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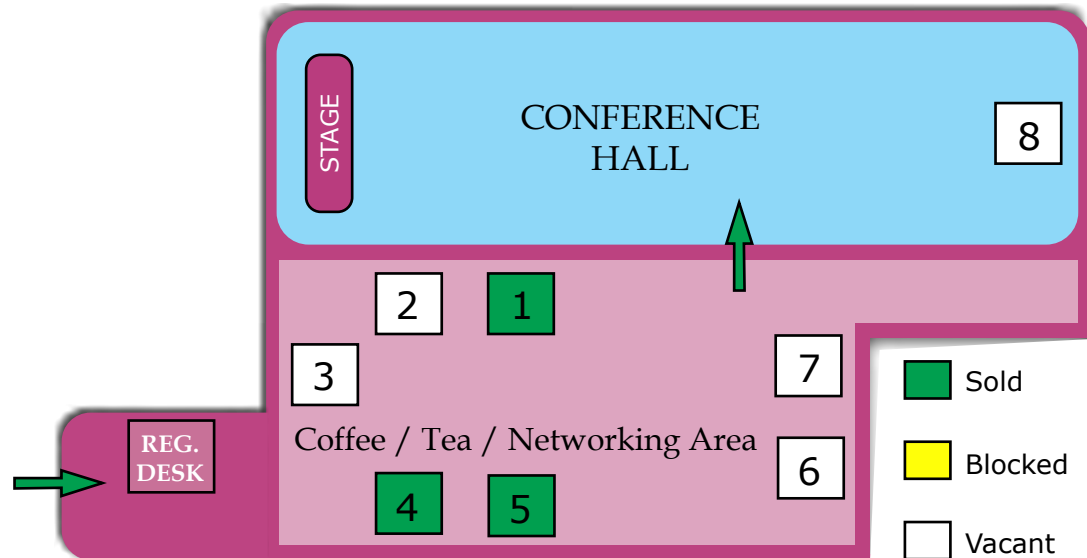
Day One

Day Two

Floor Plan

Booking Details

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



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Life Sciences

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BIostatistics & Data Experts

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

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

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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 (Subject to availability) - Please email to bookings@virtueinsight.com

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.

Payment Charges: We are a UK registered company and use Barclaycard payment gateway. Some card providers do charge a small foreign transaction fees for international payment (this is not charged from our end). If not sure please contact your card provider before making payment.

VENUE

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MAP & DIRECTIONS

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