

36th Pharmacovigilance 2024

#Vlphv

"Ensuring safer drugs to market. Latest developments in PV"

06th – 07th November 2024,
Hotel Kohinoor Continental, Mumbai, India

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 (USA)



MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates



MAYUR PARMAR
Deputy Collector, Prant Officer & SDM
Government of Gujarat



JEROZE DALAL
Head of Clinical Operations, Governance & Risk
Management, GSK



RAMESH JAGANNATHAN
VP Clinical Research & Pharmacovigilance
Bharat Serums and Vaccines



SANTOSH TAUR
Director Medical Affairs, Pfizer India &
Chair RWE Council, ISCR



VIPIN SETHI
AVP, Global Head – Pharmacovigilance
Cadila



SAKSHI SHRIVASTAVA DESAI
Associate Director International
Pharmacovigilance Strategy Realization
Johnson & Johnson



PRATIK SHAH
VP Medical Affairs
Bharat Serums and Vaccines



ANUJA JAWALE
Associate Director - RA/PV Strategic
Engagements & Vendor Management, Organon



RAHUL GUPTA
Vice President, Regulatory Affairs
USV



JAMAL BAIG
Multi Country Safety Head
Sanofi



VAIBHAV SALVI
Director & Head - Clinical Study Unit, India &
South East Asia, Sanofi



RISHI JAIN
Country Medical Head
Novartis



SOURABH FULMALI
Global Medical Director – Respiratory
GSK



ANJU AGARWAL
Global Director, Global Patient Safety
Advanz Pharma



MUKESH GORI
Associate Director -ESP Management CMO &
PS, Novartis



SHIRAZ KANDAWALLA
Associate Director
Ferring Pharmaceuticals



RAHUL SOMANI
Head- Global Pharmacovigilance
Alkem Laboratories



DILIP PAWAR
Former Head - Medical Affairs &
Pharmacovigilance, Unichem Laboratories



INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim



PRABHAT SINHA
Director Government & Public Affairs
Boehringer Ingelheim

Conceptualised By



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SRINIVASAN ACHARY
Associate Director
Cipla



MARTINA GOMES
Head, Reg Affairs – CH, South Asia
Bayer



SIVA KUMAR BUDDHA
Director PV, Head of Signal & Risk
Management, Indegene



ASWIN KUMAR
Head-Global Medical Writing
Viatris



ROSHAN PAWAR
Head Medical Affairs
Alkem Laboratories



VIVEK GUPTA
Associate Director, Clinical / Medical Affairs /
Outcomes Research Vendor Relationship
Organon



KRUNAL DALAL
Head Medical Affairs
GSK



JOYDEEP SENGUPTA
Global Pharmacovigilance - Site Head
Sun Pharmaceuticals



SADANAND KULKARNI
Head- Medical, Regulatory, Vigilance and
Quality, Fresenius Kabi



SEERA DILEEP RAJU
Senior Manager - ML & AI
MSD



RENUKA NEOGI
Head & Deputy GM - Global Clinical Quality
Management, Sun Pharma



APARNA PRABHUNE
Assistant General Manager – Regulatory Affairs
Wockhardt



SANKET NEWALE
Head Medical Affairs & Business Compliance
Wockhardt



KAVITA LAMROR
Partner, RWE & Digital Transformation
Maxis Clinical Sciences



SATISH SETHI
Head Global PV Operations & SERM
Surveillance Operations, Glenmark



GIRIJESH SRIVASTAVA
Senior Manager - Global Supply Chain | Digital
Transformation, Sun Pharmaceuticals



JYOTSNA PATWARDHAN
Cluster Head Clinical / PV QA at Africa,
Middle East, Turkey & India, Novartis



GIRISH SANE
GM & Head Pharmacovigilance
Bristol Laboratories



MAYUR MAYBHATE
Head Medical Affairs
Alkem Laboratories



RANJIT BARSHIKAR
CEO
QBD International, United Nations Adviser

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Key Speakers Include



SAKHARAM GARALE
Founder & CEO
Renovare Healthcare



PROTITI BAGCHI
Senior Manager - Digital Marketing |
Customer experience | Product Strategy, **Pfizer**



KUSHAL SARDA
GM & Head - Medical Affairs, Clinical
Research & PV, **Shalina Healthcare**



CHAITANYA KULKARNI
GM Pharmacovigilance
Marksans Pharma



VISHWAS SOVANI
Founder Director
Pharmawisdom



SUNIL NIGHOT
Manager, ICSR Quality
Kenvue (Division of J&J)



VANSHIKA BRIJUWANI
Manager Country Development Quality (CDQ)
Novartis

Plus More Coming Soon...

SILVER PARTNER

propharma

EXHIBITORS

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FOCUSED AREAS

Market Trends - Critique & Ways Forward
Challenges / Opportunities
Patient Safety
RMP / REMS
Safety & Signal Detection
Automation in PV
Regulatory
Impact of Technology AI, ML
Audits & Inspection
RWE / RWD
Outsourcing

WHO SHOULD ATTEND & WHO YOU'LL MEET

CIOs, CEOs, CDOs, Vice Presidents, Presidents, Heads, Directors and Team Leaders from the following areas:

Pharmacovigilance Strategy, Drug Safety/Risk Management, Information and Clinical Data Management, Clinical Research, Research & Development, Product Safety/Assurance Assessment, Patient Safety & Outcomes Research & Data Analysis, Epidemiology project management, Regulatory Affairs and Compliance, Sales & Marketing, Biotech manufacturers

From the following:

- Pharmaceutical organizations
- Generic pharmaceutical companies
- Contract research organizations
- Patient recruitment companies

WHY SHOULD YOU ATTEND

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 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. 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 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.

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DAY ONE - 06th November 2024

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

09:20 – Welcome Address

EVOLUTION

09:30 – Evolution of the PV ecosystem

- The PV ecosystem has evolved and requires a mindset shift – are you ready for the change?
- What to expect in the next 5 years?
- Key Challenges and industry best practices

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen (USA)

CHALLENGES & OPPORTUNITIES

10:10 – Keynote Panel Discussion: New Era of PV's
Challenges / Opportunities - Turning strategy into execution

- Discussion on strategies to address pharmacovigilance challenges in the long-term
- What comes next for the industry?
- Automating pharmacovigilance: Are we ready for the upcoming future?
- Moving forward in Drug Safety – Where are we heading and which is the right direction?
- Current challenges and goals in the field and to identify ways for betterment
- Moving towards a better future: bigger and better
- Best practices & lessons learnt today

Moderator:

VIPIN SETHI
AVP, Global Head – Pharmacovigilance
Cadila

Panellists:

RAMESH JAGANNATHAN
VP Clinical Research & Pharmacovigilance
Bharat Serums and Vaccines

PRABHAT SINHA
Director Government & Public Affairs
Boehringer Ingelheim

SAKSHI SHRIVASTAVA DESAI
Associate Director International Pharmacovigilance
Strategy Realization, Johnson & Johnson

ANUJA JAWALE
Associate Director - RA / PV Strategic Engagements &
Vendor Management, Organon

RISHI JAIN
Country Medical Head
Novartis

11:00 – Morning Coffee / Tea & Discussion

PATIENT SAFETY

11:30 – Keynote Panel Discussion: Enhancing patient
centricity & patient safety

- The What, Why, and How - Reduce Barriers and move towards prioritising patients
- Protecting patients and pharmacovigilance compliance in extraordinary circumstances
- Next generation pharmacovigilance for enhanced patient safety
- Strategy for improving your organization's patient facing communications
- Discuss specific methodologies frequently used in the development of patient safety program
- Encouraging patient support programs in Pharmacovigilance
- A practical approach to reshaping patient safety
- Educating stakeholders via patient stories

Moderator:

DILIP PAWAR
Former Head - Medical Affairs & Pharmacovigilance
Unichem Laboratories

Panellists:

VAIBHAV SALVI
Director & Head - Clinical Study Unit, India & South East Asia, Sanofi

SOURABH FULMALI
Global Medical Director – Respiratory
GSK

INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

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AGENDA AT A GLANCE

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DAY ONE - 06th November 2024

RENUKA NEOGI

Head & Deputy GM – Global Clinical Quality Management
Sun Pharma

ASWIN KUMAR

Head-Global Medical Writing
Viatris

12:20 – Topic TBC

For sponsorship opportunities please contact
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12:50 – Networking luncheon

RISK MANAGEMENT

13:50 – Panel Discussion - Risk Management – Planning for a risk-free tomorrow

- Implementation and maintenance of RMP's – Overcoming its challenges
- One RMP to fit all or all to fit within one RMP?
- Benefit/Risk ratio: the common denominator
- Implementing a Risk-Based Monitoring Solution: Understanding the basics of a sustainable model
- Key considerations in evaluating the impact of uncertainty on the quality of the benefit-risk assessment decision
- The "Next Generation" risk management tools
- Manage Risks and enhance engagement through various successful approaches
- Risk Evaluation and Mitigation Strategies (REMS): Lessons to learn today

Moderator:

RANJIT BARSHIKAR

CEO

QBD International, United Nations Adviser

Panellists:

JEROZE DALAL

Head of Clinical Operations, Governance & Risk Management, GSK

JAMAL BAIG

Multi Country Safety Head
Sanofi

SIVA KUMAR BUDDHA

Director PV, Head of Signal & Risk Management
Indegene

14:40 – RMP - Importance of getting the right aRMM's

JAMAL BAIG

Multi Country Safety Head
Sanofi

15:10 – Afternoon Tea / Coffee

QUALITY - SAFETY

15:40 – From Compliance to Excellence: The future of Patient Safety

- Introduction to Patient Safety
- What has changed
- Fundamentals remain unchanged
- Shift the focus
- Implementation strategy
- Conclusion and take aways

ANJU AGARWAL

Global Director, Global Patient Safety
Advanz Pharma

REGULATORY

16:10 – Keynote Panel Discussion: PV - Regulatory Updates – Transforming regulatory strategy to meet the evolving landscape in Prioritising Patients

- Key current changes and their impact on current PV
- Integrating patient focus into the regulatory mindset
- Regulations on adverse events / Guidelines for critical medicines
- Future Legislation: Pharmacovigilance Industry Vision
- PV system legislation updates
- Improving communication between regulators, regional authorities and patients
- Standardizing and streamlining the regulatory process
- What's next? Ways to proceed forward.

Moderator:

MILIND ANTANI

Leader, Pharma and Healthcare
Nishith Desai Associates

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MAYUR PARMAR
Deputy Collector, Prant Officer & SDM
Government of Gujarat

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

SHIRAZ KANDAWALLA
Associate Director
Ferring Pharmaceuticals

MARTINA GOMES
Head, Reg Affairs – CH, South Asia
Bayer

.....
17:00 – Welcome address for Networking Drinks

4C Pharma Solutions

.....
17:05 – 18:15 – Networking Drinks
.....



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Sponsorship Enquires - info@virtueinsight.com

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DAY TWO - 07th November 2024

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

09:20 - Topic TBC

ROSHAN PAWAR
Head Medical Affairs
Alkem Laboratories

IMPACT OF TECHNOLOGY

09:50 - Panel Discussion - Technology: Unlocking the better ways in PV

- How long can AI, process automation and improvements give a hand in PV?
- Digital Adverse event monitoring and Electronic Health Records - What are the risks and benefits?
- ML in patient monitoring: How do industrial experts see this?
- Regulatory decision - making: In what way AI makes the path easier?
- Data management and control in PV
- Solving the challenges in PV by using Cloud

Moderator:

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare

Panellists:

SEERA DILEEP RAJU
Senior Manager - ML & AI
MSD

SRINIVASAN ACHARY
Associate Director
Cipla

PROTITI BAGCHI
Senior Manager - Digital Marketing | Customer experience | Product Strategy, Pfizer

GIRIJESH SRIVASTAVA
Senior Manager - Global Supply Chain | Digital Transformation, Sun Pharmaceuticals

MOVING FORWARD - 2025

10:40 - Pharmacovigilance for 2025 - Moving forward positively

- Future horizons and efficiencies in data acquisition, evaluation and risk management
- Future-proofing Safety Systems
- Where are we?
- Boldly Shaping the Future

11:10 - Morning Coffee / Tea & Discussion

AUDITS & INSPECTIONS

11:40 - Panel Discussion - Managing Pharmacovigilance Audits & Inspections

- Staying ahead in the race - Current trends for and future guidelines
- How to prepare and what to expect?
- Remote audits and inspections - Logistical issues
- PV Inspection readiness: Keeping on the right side of inspectors
- Methodologies, scope and oversight
- Boldly shaping the future
- What has this pandemic thought us towards audits and inspections?

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

JYOTSNA PATWARDHAN
Cluster Head Clinical / PV QA at Africa, Middle East, Turkey & India, Novartis

VIVEK GUPTA
Associate Director, Clinical / Medical Affairs / Outcomes Research Vendor Relationship, Organon

JOYDEEP SENGUPTA
Global Pharmacovigilance - Site Head
Sun Pharmaceuticals

CHAITANYA KULKARNI
GM Pharmacovigilance
Marksans Pharma

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SUNIL NIGHOT
Manager, ICSR Quality
Kenvue (Division of J&J)

12:30 – Topic TBC

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13:00 – Networking luncheon

RWD / RWE

14:00 – Panel Discussion - Real World Data to Real World Evidence

- Importance of real-world data for answering regulatory questions
- Benefits and challenges of evidence derived from real world sources compared to clinical trials.
- Real World Evidence: How Does its Use challenge quality and compliance programs?
- Obtaining patient-centric using RWE
- What are complications that will rise by inserting new data source? Breakup in data?
- Identify the challenges involved in incorporating real world evidence into a structured benefit-risk assessment.

Moderator:

KAVITA LAMROR
Partner, RWE & Digital Transformation
Maxis Clinical Sciences

Panellists:

PRATIK SHAH
VP Medical Affairs
Bharat Serums and Vaccines

SANTOSH TAUR
Director Medical Affairs, Pfizer India &
Chair RWE Council, ISCR

KRUNAL DALAL
Head Medical Affairs
GSK

MAYUR MAYBHATE
Head Medical Affairs
Alkem Laboratories

SANKET NEWALE
Head Medical Affairs & Business Compliance
Wockhardt

VANSHIKA BRIJWANI
Manager Country Development Quality (CDQ)
Novartis

KUSHAL SARDA
GM & Head - Medical Affairs, Clinical Research & PV
Shalina Healthcare

MEDICAL DEVICES

14:50 – Perspectives of Materiovigilance

- Pharmacovigilance and Emergence of Materiovigilance
- Understanding Materiovigilance
- Global Regulations on materiovigilance
- Materiovigilance in India

APARNA PRABHUNE
Assistant General Manager – Regulatory Affairs
Wockhardt

15:20 – Afternoon Tea / Coffee

OUTSOURCING

15:40 – Panel Discussion – PV and Outsourcing - How to evaluate and implement sourcing alternatives?

- Benefits and risks of managing a pharmacovigilance-out-sourced organization
- Steps to be taken in order to maintain efficacy and quality
- Outsourcing - Best Practices, Challenges and key consideration in choosing right vendor
- Preliminary set up steps – What are all to be looked into?
- Future of the field of pharmacovigilance, with a focus on how collaborations can work to advance the industry in this space?
- Updates & lessons learned from novel approaches for collaborations while outsourcing
- Outsourcing vs Innovation
- Importance of Proper communication between - Sponsor - Site - CRO - Patients

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

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Panellists:

MUKESH GORI

Associate Director -ESP Management CMO & PS
Novartis

RAHUL SOMANI

Head- Global Pharmacovigilance
Alkem Laboratories

SADANAND KULKARNI

Head- Medical, Regulatory, Vigilance and Quality
Fresenius Kabi

SATISH SETHI

Head Global PV Operations & SERM Surveillance
Operations, Glenmark

GIRISH SANE

GM & Head Pharmacovigilance
Bristol Laboratories

.....
16:30 - Closing remarks and end of conference
.....

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 - info@virtueinsight.com

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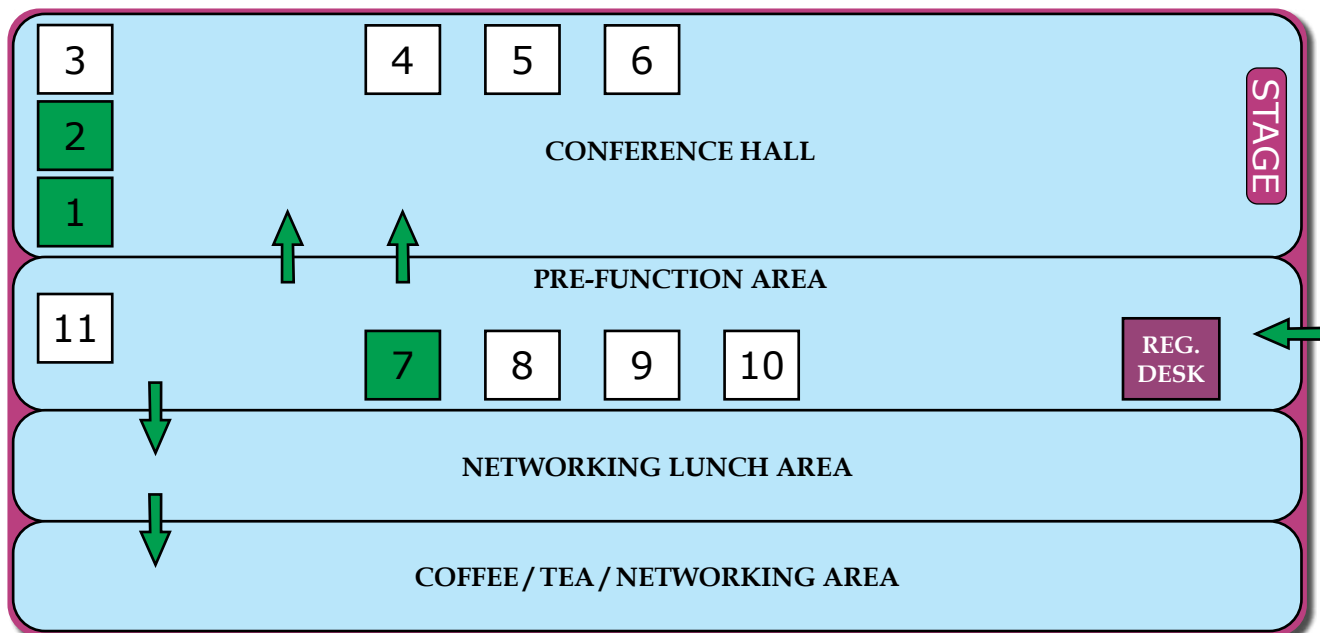
Floor Plan

Booking Details

 Sold

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☐ Vacant



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

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REGISTER ONLINE :

Link : <https://konfhub.com/virtue-insights-pharmacovigilance-2024>

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

REGISTRATION FORM

RESERVATION PRICING:

Super Early Bird Price (Valid Till 13th September 2024)

Cost per delegate - Fee: INR 14,000 + GST(18%)

Standard Price

Cost per delegate - Fee: INR 19,000 + GST(18%)

Please email us at bookings@virtueinsight.com

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Company

GST No (If Applicable)

Official Contact Number

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Country Postcode

Phone Fax

Email

I confirm that I have read & agree to the terms and conditions of booking..... (Please Tick) ☐

Signature

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Queries:

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General Information Venue:

Kohinoor Continental Hotel
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Fee: The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

Covid Situation, Natural Calamity, National Security: In the case where the government of Maharashtra decide to go into a lockdown or restrictions on social and business gatherings during the dates of the conference, the event will be postponed to a new date. Registered clients can choose to join the conference on the new date or decide to take a credit note for their payment so that they can decide to participate for any of our future events within the timeframe of next one year.

VENUE

Kohinoor Continental Hotel

Address: Andheri Kurla Road,
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Mumbai - 400059,
India.

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HERE
for more details

MAP & DIRECTIONS

Conceptualised By



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