26th Pharmacovigilance 2021

"Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management"

11th November 2021, Virtual Conference (Time Zone – IST)

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

K BANGARURAJAN
Adviser
CDSCO (New Delhi)

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

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation, Takeda (Belgium)

KLAUDIJA MARIJANOVIĆ BARAĆ
Sr Director, Global Patient Safety & PhV
Teva (UK)

ROHAN MANE
Director, Risk Management Product Lead
Pfizer (UK)

TEA BABIC
Director, PV Audits and Inspections
Teva Pharmaceuticals(UK)

MAHESH MURTHY
Sr. Director of Operations - Medical Device
Biocon

SUBHASH C MANDAL
VP and Chairman, Regulatory Affairs Division
Indian Pharmaceutical Association

ANIL KUKREJA
Vice President - Medical Affairs and Regulatory
AstraZeneca

NISHITH TYAGI
Director (Data Science and AI Solutions)
Novartis

PRAVEEN RAJ
Senior Director Medical Affairs
Biocon

RAJEEV SHRIVASTAVA
Associate Director - Regulatory Affairs and Pharmacovigilance, Eli Lilly

VAIBHAV CHOUDHARY
Joint Director, Medical and Clinical Affairs
Fresenius Kabi Oncology

KAVITA LAMROR
Director, Real World Investigator
Sanofi

KARTHIKEYAN KUMARAN
Associate Director of Information Technology
AstraZeneca

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

DNYANESHWAR SANAP
EU/UK QPPV, Head Regional Pharmacovigilance, Glenmark (Germany)

AVINASH R. KAKADE
SGM, Global Head – Pharmacovigilance
Lupin

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

VEENA RAJAN
Head Mature Products PV, Global Patient Safety
AstraZeneca

Conceptualised By

Virtue Insight

+91 44 42108101

info@virtueinsight.com

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JAIDEEP GOGTAY
Chief Medical Officer
Cipla

GEETA SHANBHAG
Sr. General Manager – Pharmacovigilance & Medico-Regulatory Affairs, Ipca Laboratories

JYOTSNA PATWARDHAN
Cluster Head, PV Country Quality
Novartis

JAMAL ANWAR
Country Head- Pharmacovigilance
Merck Sharp and Dhome

INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

VALLABH DESHPANDE
Head of Global PV Operations
Glenmark

VISHWAS SOVANI
Founder Director
Pharmawisdom

RAJENDRA KUMAR KASI
Head - Global Pharmacovigilance
Zydus Cadila Healthcare

ROSHAN PAWAR
Associate General Manager
Alkem Laboratories

RAGHDA MOHAMED
PV Cluster Lead Middle East & Turkey
Takeda (UAE)

VARSHA NARAYANAN
Founder-Director
Dr Varsha's Health Solutions

GAYATHRI DEVI RAVICHANDRAN
Associate Manager - Regional Safety Operations, Merck

KAVYA KADAM
Consultant, Global Clinical Trials

SAKSHI SHRIVASTAVA DESAI
Global Medical- PV Compliance Strategy and Analytics, Johnson & Johnson

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CONFERENCE INTRODUCTION

Virtue insight's **26th Pharmacovigilance Conference** is more than a traditional conference. It is a unique opportunity to learn about the latest trends, to engage with renowned experts, and to personally develop as a healthcare professional. The 26th Pharmacovigilance Conference will take place on 11th November 2021

According to recent report, the worldwide market for PV outsourcing was worth more than $3.8 billion in 2019, and will expand at a compound annual growth rate of around 15.8% to reach $10.6 billion in 2026'. One factor in this dynamic growth is sharp year-to-year increases in PV reporting to regulatory authorities. The global pharmacovigilance market size is expected to reach USD 14.95 billion by 2028. It is expected to expand at a CAGR of 11.5% from 2021 to 2028.

The U.S. Food and Drug Administration (FDA) received approximately 253,017 serious adverse events and 44,693 deaths associated with ADRs in 2015. This shows the potential demand for implementing safety and Pharmacovigilance (PV) services. ADRs are responsible for almost 1,300,000 emergency department visits annually. Estimated the cost of ADR related hospitalizations in 2011 to be US $38.9 billion dollars.

Take this opportunity to learn from regulators and leading experts and discover what the challenges and opportunities will be in the field of Pharmacovigilance in 2021. Do not miss out on these exciting discussions. Join us virtually to discover and learn from the experts who will be joining us on 11th November 2021.

We look forward to seeing you virtually.

KEY THEMES DISCUSSED

- Signal detection and medical devices in PV
- How to improvise where medical devices help to improve the quality of patient care?
- Better standardization and review of REMS
- Challenges and impact of new technology in PV
- How to do better quality management system?
- What are the recent changes in Pharmacovigilance Guidelines?
- Recent improvements in COVID-19 Vaccine Research in PV – What to learn from it for future?
- Patient centric in Pharmacovigilance – Placing patients first
- Challenges in monitoring the patient in PV and Clinical trials
- Usage of electronic health records (EHR)
- Patient safety monitoring in social media: What are the troubles?
- Current Risk Management planning strategies in PV
- Current trends in PV Audits and Inspections
- Machine learning for detection of signals? How ML improve the PV than before?
- Real World Evidence in PV
- Impact of AI in Pharmacovigilance and how data analytics are increase the speed of PV?
- Automation leads the way of Future PV
- Risk and awareness of Robotics in PV
- New regulatory guidelines
- Be part of a major networking opportunity

WHO SHOULD ATTEND AND 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, Government- Department of health, Non-profit organizations/ Association, Consultants

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.

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DAY ONE - 11th NOVEMBER 2021

09:20 - Welcome Address & Virtual Conference Platform Instructions

MEDICAL DEVICE & REGULATORY

09:30 – Topic TBC

MAHESH MURTHY
Sr. Director of Operations - Medical Device
Biocon

10:00 – DISCUSSION WITH EXPERTS: A new way towards Pharmacovigilance Regulations

- New regulatory guidelines for pharmacovigilance
- How are companies expected to fulfil their needs on the way to new regulations?
- New regulations on Drug Research & Development
- Evaluating real-world evidence sources by regulators
- What could be new skills for a new PV?
- Pharmacovigilance from the Medical Affairs Perspective

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

K BANGARURAJAN
Adviser
CDSCO (New Delhi)

SUBHASH C MANDAL
Vice President and Chairman, Regulatory Affairs Division
Indian Pharmaceutical Association

ANIL KUKREJA
Vice President - Medical Affairs and Regulatory
AstraZeneca

PRAVEEN RAJ
Senior Director Medical Affairs
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VAIBHAV CHOUDHARY
Joint Director, Medical and Clinical Affairs
Fresenius Kabi Oncology

GEETA SHANBHAG
Sr. General Manager – Pharmacovigilance & Medico-Regulatory Affairs, Ipca Laboratories

11:00 – Morning Coffee/Tea & Discussion

PATIENT SAFETY & RISK MANAGEMENT

11:10 – DISCUSSION WITH EXPERTS: To improve Patient Outcomes and Patient-Centric in Pharmacovigilance

- How to maintaining patient safety and to ensure product quality?
- Recent challenges in monitoring the patient and usage of Electronic health records (EHR)
- How to rectify the risks of potential signals detection, risk management, protocol amendments and scientific data integrity?
- What are barriers to patient access, and sustainability of risk?
- Encouraging the patient for direct reporting the adverse effect on drugs
- How to improve the usage of remote wearable devices for patient-centric trials?
- Patient safety monitoring in social media: What are the troubles?
- Building better outcomes through integrated technology to monitor quality and improve patient outcomes.

Moderator:

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

Panellists:

RAJEEV SHRIVASTAVA
Associate Director - Regulatory Affairs and Pharmacovigilance, Eli Lilly

JYOTSNA PATWARDHAN
Cluster Head, PV Country Quality
Novartis

VEENA RAJAN
Head Mature Products PV, Global Patient Safety
AstraZeneca

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RAGHDA MOHAMED
PV Cluster Lead Middle East & Turkey
Takeda (UAE)

ROSHAN PAWAR
Associate General Manager
Alkem Laboratories

12:00 – DISCUSSION WITH EXPERTS: Risk Management planning strategies in PV

- Growth and Operations of REMS – Challenges and Mitigations
- Understanding the risk management planning, and risk communication in PV
- Discussing about the strategies that support the PV from beginning to end
- Analyzing risk quantification and benefit assessment
- How does REMS work?
- Better standardization and review of REMS
- Measuring the value of risk management plans and risk evaluations and mitigation strategies.
- Better/strong quality management system

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation
Takeda (Belgium)

KLAUDIJA MARIJANOVIĆ BARAĆ
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INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

SAKSHI SHRIVASTAVA DESAI
Global Medical- PV Compliance Strategy and Analytics
Johnson & Johnson

13:00 - Networking luncheon

ML, DIGITALIZATION & TECHNOLOGIES

13:40 – Combination of ML and Digitalization in PV

- How digital PV is growing in India?
- Digitalization helps to increase drug discovery?
- Digitalization give hands for safety case reports management
- Identify unusual cases or data errors by using ML
- Machine learning for detection of signals.
- ML provides best Practices in safety case management

14:10 - Solution Provider Presentation

For sponsorship opportunities please contact
info@virtueinsight.com

14:40 – DISCUSSION WITH EXPERTS: How RWE, Data and AI make better Pharmacovigilance practices and Impact of technology for tomorrow

- Real World Evidence in PV
- Challenges in the accessing data collection.
- AI has become an integral part of pharmacovigilance
- Improving the usage of Robotics and Big data in PV.
- Big data analytics using AI can help in drug discovery? Solving the safety issues by AI
- Risk and awareness of Robotics in PV
- In what ways COVID-19 affected the digital transformation of Pharmacovigilance?
- How do we guarantee RWD measures are effective?
- Automation leads the way of Future PV

Moderator:

NISHITH TYAGI
Director (Data Science and AI Solutions)
Novartis

Panellists:

KAVITA LAMROR
Director, Real World Investigator
Sanofi

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DAY ONE - 11th NOVEMBER 2021

KARTHIKEYAN KUMARAN
Associate Director of Information Technology
AstraZeneca

VARSHA NARAYANAN
Founder-Director
Dr Varsha's Health Solutions

KAVYA KADAM
Consultant, Global Clinical Trials

PV AUDITS, INSPECTION & CHALLENGES

15:20 – PV partners auditing: how to focus on what matters most

- Which topics are relevant vs. non relevant for a certain type of relationship
- From where to get the data for audit planning
- QMS requirements

TEA BABIC
Director, PV Audits and Inspections
Teva Pharmaceuticals(UK)

15:50 – Afternoon Tea/Coffee

16:10 – DISCUSSION WITH EXPERTS: Recent challenges in Pharmacovigilance and areas for improvisations

- What are the recent safety standards for pharmaceutical products?
- Analyzing important changes in Pharmacovigilance Guidelines
- How to increase the speed of signal detection by data analytics?
- Monitoring adverse effects during PV
- A next-generation advancement towards pharmacovigilance
- Uses of combining secondary sources in pharmacovigilance
- Recent improvements in COVID-19 Vaccine Research in PV – What to learn from it for future

Moderator:

Panellists:

AVINASH R. KAKADE
SGM, Global Head – Pharmacovigilance
Lupin

JAIDEEP GOGTAY
Chief Medical Officer
Cipla

VALLABH DESHPANDE
Head of Global PV Operations
Glenmark

RAJENDRA KUMAR KASI
Head - Global Pharmacovigilance
Zydus Cadila Healthcare

GAYATHRI DEVI RAVICHANDRAN
Associate Manager - Regional Safety Operations
Merck

16:50 – FDA's Post-Market Safety Reporting Requirements (PMSR) – one year post-implementation journey

- Challenges faced by stakeholders during and post implementation of PMSR requirements
- Organizational Challenges faced by industry
- Differences in impact for Combination products that are device-led vs. Drug-led

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

17:30 - End of conference

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Link : https://www.townscript.com/e/26th-pharmacovigilance-2021-023014

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

REGISTRATION FORM

RESERVATION PRICING:

EARLY BIRD PRICE

Cost per delegate

Fee: INR 6,000 + GST(18%) (Valid Till 27th September 2021)

STANDARD PRICE

Cost per delegate

Fee: INR 8,000 + GST(18%) (Valid From 28th September 2021)

Discounted Rate for Bulk Booking of More Than 5 Delegates

Please email us at **bookings@virtueinsight.com**

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Company .....

GST No (If Applicable) .....

Official Contact Number .....

Address .....

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

Signature .....

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CERTIFICATION

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

Queries:

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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.

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