20th Pharmacovigilance 2019

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

07th November 2019,
Kohinoor Continental Hotel,
Mumbai, India

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

KAMAL K HALDER
ADCI
CDSCO (WZ)

OMPRAKASH S. SADHWANI
Former Joint Commissioner and controlling Authority
Food and Drug Administration (Maharashtra State)

JEAN-DOMINIQUE
Subject Matter Expert - PV & Drug Safety
Elsevier (France)

DEEPA ARORA
Director
CLINEXEL Life Sciences

UJWALA NAIK
Country Head-Pharmacovigilance
Johnson & Johnson

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

SHIVANI ACHARYA
Associate Director – Clinical Development & PV
Abbott

INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

ARUN BHATT
Consultant – Clinical Research & Development

KARTHIK BABU
Multi Country Safety Head-South Asia
Sanofi

SRIRUPA DAS
Director - Medical Affairs
Abbott

MANOJ SWAMINATHAN
Chief Manager Head Global Pharmacovigilance Center
Piramal

RANJIT BARSHIKAR
QbD / CGMP Consulting, Member Editorial Board
Journal of Generic Medicines, England

ROSHAN PALEWAR
CEO, Pharma Global Leader
DocRoShGlobal Solutions

CHIRAG TELI
Head of Medical Services
Alkem Laboratories

PAVAN BADALE
Head PV Process Excellence Safety case Management
Novartis

DHANARAJ E
Pharmacovigilance Lead
Biocon

CHAITANYA KULKARNI
Manager Pharmacovigilance
Brillpharma (Subsidiary of Bristol Labs, UK)

UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

PRADEEPA RAMAKRISHNA
Global Safety Physician Lead Surveillance Physician
AstraZeneca

ANANT PATIL
Asst Professor Department of Pharmacology
Dr DY Patil Medical College

SOFI JOSEPH
Head of Regulatory Affairs and Pharmacovigilance
Serdia Pharmaceuticals

VISHWAS SOVANI
Founder Director
Pharmawisdom

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"Very well organised & very interesting topics selected. Time management & allowing to ask questions were very sufficient as well."

Head of Clinical Operations - Emerging Markets, Boehringer Ingelheim

AGENDA AT A GLANCE

KAVYA KADAM
Consultant Global Clinical Trials

PRANJAL BORDOLOI
Vice President – Clinical, Medical Affairs & PV
Veeda Clinical Research

SAKHARAM GARALE
Head South-East Asia Operations ACMA & Managing Partner
RENOVARE Healthcare Solutions

PRASHANT BODHE
Director
CliniSearch

Plus many more COMING SOON.....

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"Great opportunity for networking and to learn different industry perspectives on PV systems, challenges & regulations."

Regulatory Inspection Lead, Safety & International Global Quality, Takeda

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

Present review described Pharmacovigilance and drug safety in India. Challenges related to Pharmacovigilance programme, roles of physicians/health professionals as well as role of public/patients for successful monitoring are discussed herewith as nowadays, in India a safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug as ever-increasing range and potency of medicines. A successful Pharmacovigilance programme related to drug safety should be able to answer the key questions. How quickly has the case been identified? As well as what proportion of patient has successfully monitored collectively by doctor, Pharmacist/health professionals. As early detection is the key in reducing adverse events to minimum level or at lateral stage it may be a fatal or challenge to the health professionals. Challenges related to Pharmacovigilance programme in India can be avoided by strictly implementing proper rule and regulation everywhere. Strengthening of public campaigns for drug safety to improve awareness, addition of drug safety study to the curriculum, minimising the level of adverse effects by having sound knowledge about the side effect of the drug as day by day increasing number of medicines may help in monitoring the Pharmacovigilance programme. Interestingly, Improvement of communication regarding Pharmacovigilance between public and health professionals creates awareness so as to minimize adverse occurring. Proper knowledge on Pharmacovigilance would help to health professionals to understand the effectiveness or risk of medicines that they prescribe and ensure a better healthcare to patient.

Virtue Insight's 20th Pharmacovigilance 2019 Conference provides the strongest context, background, updates, new developments, and future direction for regulations and guidance on safety, pharmacovigilance, and risk management strategies that cannot be found in any other meeting. The content of this event is developed by top experts from the biopharmaceutical industry and global regulatory agencies, and Virtue Insight will convene the best speakers from around the world to discuss the current challenges and issues that matter most to professionals working in the field.

We look forward to seeing you personally at our esteemed event.

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Pharmacovigilance and social media: An industry view
- Addressing a number of technical, regulatory and ethical challenges
- Traditional medicines and herbal of pharmacovigilance: Solutions and innovations
- Herbal medicines uses: Developing reliable information on safety
- Discussing on the global pharmacovigilance system for India
- Recent development of pharmacovigilance system in India
- Insure safe use of medicines and minimizing the risks related to the medicinal product
- Data generated during clinical trials to provide information about the common adverse events
- Pharmacovigilance: Guidance of biologics and biosimilars
- Monitoring the safety of biologics and biosimilars
- Pharmacovigilance Analytics: The hype of big data for pharmacovigilance
- Establishing the age of big data in pharmacovigilance
- Real-world example of the development of a successful risk management plan
- How to write a successful risk management plan
- The current regulatory framework and its global impact
- Implications for the global environment
- Understanding the global regulatory developments and updates
- New regulatory policy, development, and review
- Be part of a major networking opportunity

AN EVENT TO VOW

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.

WHY EXHIBIT?

Make Sales
Debut new products
Profile your brand
Meet new business partners
Develop key relationships
Educate pharma and biotech companies

WHO WILL YOU MEET

Vice Presidents, Directors, CRO's, Heads and Managers of:

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

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"Insightful sessions, well structured presentations and speakers sharing highly valuable knowledge and experience. Learned a lot even through the networking breaks."

PhV Manager, Teva Pharmaceutical

AGENDA AT A GLANCE

DAY ONE - 7th November 2019

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

09:20 Chairperson opening remarks

RANJIT BARSHIKAR
QbD / CGMP Consulting
Member Editorial Board Journal of Generic Medicines, England

MARKET OVERVIEW & ANALYSIS

09:30 Pharmacovigilance Perceptions : Protection of Patients

ARUN BHATT
Consultant – Clinical Research & Development

10:00 'Improving effectiveness and compliance of literature screening – Automation, prioritization and outsourcing'.

JEAN-DOMINIQUE
Subject Matter Expert - Pharmacovigilance and Drug Safety
Elsevier (France)

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 DISCUSSION WITH EXPERTS: Discussing on the global pharmacovigilance system for India

- Recent development of pharmacovigilance system in India
- Rising pharmacovigilance issues & business models
- Automating pharmacovigilance processes: Are we already for the upcoming future?
- Improving patient safety and creating crucial awareness to enhance for better clinical practice
- Challenges and process of adverse drug reaction reporting system in India
- How digital transformation and AI can impact pharmacovigilance
- Challenges to implement rules and regulation related to pharmacovigilance program in India and can it be avoided

Moderator:

RANJIT BARSHIKAR
QbD / CGMP Consulting
Member Editorial Board Journal of Generic Medicines, England

Panellists:

UJWALA NAIK
Country Head-Pharmacovigilance
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Director - Medical Affairs
Abbott

MANOJ SWAMINATHAN
Chief Manager Head Global Pharmacovigilance Center
Piramal

DHANARAJ E
Pharmacovigilance Lead
Biocon

11:40 DISCUSSION WITH EXPERTS: Ensure safe use of medicines and minimizing the risks related to the medicinal product

- Data generated during clinical trials to provide information about the common adverse events
- Monitor safety during the post-approval period and through out the entire lifecycle of the medicinal product
- Implementing risk management programs by data mining pharmacovigilance safety databases and signal detection
- CDER and FDA: Highlighting the depth and versatility of drug safety initiatives
- Developing drug safety reporting platform that automates complex processes to ensure compliance in the regulatory environment
- Monitoring safety reporting and agreements – what needs to be covered? And what happens if it goes wrong?

Moderator:

PRASHANT BODHE
Director
CliniSearch

Panellists:

OMPRAKASH S. SADHWANI
Former Joint Commissioner and controlling Authority
Food and Drug Administration (Maharashtra state)

DEEPA ARORA
Director
CLINEXEL Life Sciences

ARUN BHATT
Consultant – Clinical Research & Development

PRADEEPA RAMAKRISHNA
Global Safety Physician Lead Surveillance Physician
AstraZeneca

ANANT PATIL
Asst Professor Department of Pharmacology
Dr DY Patil Medical College

KAVYA KADAM
Consultant Global Clinical Trials

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"The conference was very well organised and speakers were clear and concise. I enjoyed the panel discussions as it was good to hear different opinions which are based on experiences etc."

Manager – Pharmacovigilance, Kinapse (Syneos Health)

AGENDA AT A GLANCE

DAY ONE - 7th November 2019

12:30 - Networking luncheon

Afternoon Chair Person

PRASHANT BODHE
Director
CliniSearch

13:50 Pharmacovigilance of biosimilars

DEEPA ARORA
Director
CLINEXEL Life Sciences

14:20 DISCUSSION WITH EXPERTS: Real-world example of the development of a successful risk management plan

- Essential risk management plans from an industry point of view
- How to write a successful risk management plan
- Necessary aspects of managing biopharmaceutical product risks and benefits in health care delivery system
- Reporting results of outcomes of activities in the risk management plan
- The regulatory framework for pharmacovigilance in the context of risk management planning
- Stimulating pharma and drug industry for pharmacovigilance practice and software's to use in pharmacovigilance and clinical trials.
- Risk based strategies for safety issues in immuno-oncology
- Updating risk management plan

Moderator:

PRANJAL BORDOLOI
Vice President Clinical Medical Affairs & Pharmacovigilance
Veeda Clinical Research

Panellists:

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Head Pharmacovigilance
Boehringer Ingelheim

CHIRAG TELI
Head of Medical Services
Alkem Laboratories

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

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Head South-East Asia Operations ACMA & Managing Partner
RENOVARE Healthcare Solutions

CHAITANYA KULKARNI
Manager Pharmacovigilance
Brillpharma (Subsidiary of Bristol Labs,UK)

UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics

15:10 – Afternoon Tea/Coffee

REGULATORY

15:30 The current regulatory framework and its global impact

SHIVANI ACHARYA
Associate Director – Clinical Development & Pharmacovigilance, Abbott

16:00 DISCUSSION WITH EXPERTS: Understanding the global regulatory developments and updates

- New pharmacovigilance guidance in India: Expectation that can significantly change the pharmaceutical safety landscape
- Explaining principles and guidelines for planning and preparing responses to inspection observations
- Plan and conduct a response to inspect observe, including development of a CAPA, measurement, and tracking
- Addressing progression on global harmonization of pragmatic safety requirements
- Regulatory perspective on machine learning in pharmacovigilance
- Challenges in new regulatory policy and development of diagnostic products that combine drugs, devices and biological products
- Emerging pharmacovigilance regulations in emerging markets
- Regulatory trends in clinical safety & pharmacovigilance
- New regulatory policy, development, and review

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

KAMAL K HALDER
ADCI
CDSCO (WZ)

RAHUL GUPTA
Vice President, Regulatory Affairs,
USV

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Associate Director – Clinical Development & Pharmacovigilance
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Multi Country Safety Head-South Asia
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"Good opportunity to network with colleagues. Mostly the speakers/panel members were of high calibre and experienced."

Safety Executive Director, Amgen

DAY ONE - 7th November 2019

SOFI JOSEPH
Head of Regulatory Affairs and Pharmacovigilance
Serdia Pharmaceuticals

PAVAN BADALE
Head PV Process Excellence Safety case Management
Novartis

16:50 - **Chairperson's closing remarks and end of conference**

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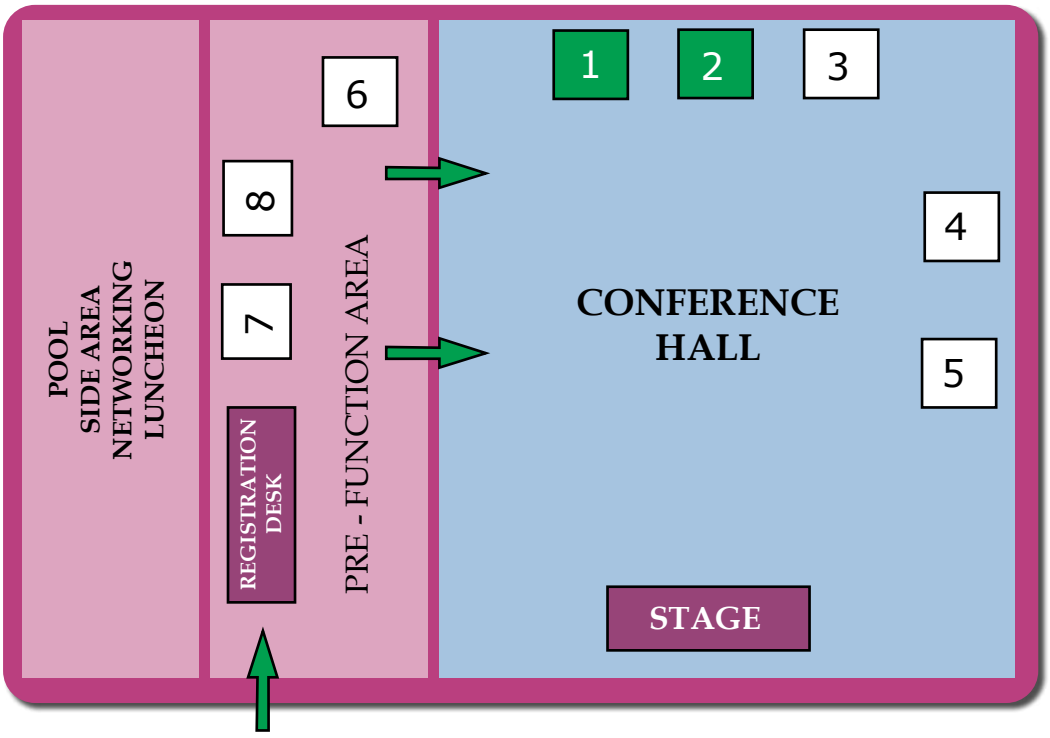
"A great platform to understand the current practices & situation all across the industry, as well as individual approach of each company toward the goal of patient safety."

Senior Executive, Lupin

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



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"Really top-tier collaboration and experts present at this event. From amazing hosts and chairman to a wonderful venue, this is the PV event that will make an impact on the industry for how we change how we do work."

Head of Clinical Quality, Karyopharm Therapeutics

AGENDA AT A GLANCE

REGISTER ONLINE :

Link : https://www.bookmytrainings.com/catalogue/event/72619-20th-pharmacovigilance-2019

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NEFT / IFSC Code	- UTIB0000211
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Queries:
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General Information Venue:
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VENUE

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MAP & DIRECTIONS

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