17th Pharmacovigilance 2018

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

15th November 2018,
Kohinoor Continental Hotel,
Mumbai, India

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

A. RAMKISHAN
Deputy Drugs Controller, DDC(I)
CDSCO

K. BANGARURAJAN
Joint Drugs Controller (INDIA)
CDSCO (HQ)

RAJENDRA SANGHAVI
Sr. Consulting Clinician & Chairman - Medical Committee
Indian Drug Manufacturers' Association (IDMA)

MAYUR PARMAR
Deputy Collector
Government Of Gujarat

DEEPA ARORA
Vice President- Pharmacovigilance & Global Head- Drug Safety & Risk Management
Lupin

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

ARUN BHATT
Consultant – Clinical Research & Development

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

JAMAL BAIG
Country Head- Pharmacovigilance
Merck Sharp & Dohme

SANJEEV MIGLANI
Founder and Director
AWINSA Life Sciences

GURPREET SINGH
Global Head, Pharmacovigilance Operations
Novartis

SRIRUPA DAS
Associate Director - Medical Affairs
Abbott

PRADEEPA RAMAKRISHNA
Global Safety Physician/ Lead Surveillance Physician
AstraZeneca

MANOJ SWAMINATHAN
Chief Manager / Head - Global Pharmacovigilance Center
Piramal

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

ALAP GANDHI
Head, Medical Affairs
GSK

SAKHARAM GARALE
General Manager, Medical Affairs & Public Health
Mylan Laboratories

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

NIDHI VAISH DAS
Drug Safety
Roche Pharmaceuticals

PRASHANT BODHE
Director
CliniSearch

SUJAY KULKARNI
Senior Manager, Clinical Research and Pharmacovigilance
Glaxo Smith Kline (GSK)

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

PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

Plus many more COMING SOON.....

WHO ATTENDS?

- **30+** Speakers
- **70%** Pharma / Biotech
- **3+** Hours of Networking
- **1** Day
- **1** Golden Opportunity

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"Very good platform to meet other pharmacovigilance expertise and interact with them about the advances & opportunites in pharmacovigilance. Virtue Insights is really good at coordinating and organizing."

Safety Physician, Sciformix

AGENDA AT A GLANCE

PRINCIPAL PARTNER

APCER LIFE SCIENCES
Together for better health

GOLD PARTNER

Syneos Health

EXHIBITOR

AB-Cube
Making Safety Easy

MedVigil

ELSEVIER

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"Very nice opportunity to share own challenges with other Pharmacovigilance experts and hear about future initiatives. I would like to thank Virtue Insight for organising the conference"

Associate Director, Pharmacovigilance Operations, INCYTE Biosciences International

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

Pharmacovigilance is uniquely placed to nurture sharing of good practice between industry representatives and seeking advice from regulators and inspectors as we all strive to improve the way we manage patient safety and comply with legislation.

Virtue Insight has worked close with Industry and Regulators to bring topics and speakers together with broad audiences in order to create stimulating and relevant discussion.

We are glad to announce the 17th Pharmacovigilance 2018 to be held on 15th November 2018 in Mumbai, India. It focuses on the advancements in Pharmacovigilance, Risk Management, and Drug Safety.

The field of Pharmacovigilance is growing rapidly and its development is making tremendous impacts in medical sciences and pharmaceuticals. 17th Pharmacovigilance 2018 emphasizes on how the importance and significance can be gauged by the fact that it has made huge advancements over the course of time and is continuing to influence various sectors.

Why to attend?

With members from around the world focused on learning about Pharmacovigilance and its advances; this is your best opportunity to reach the largest assemblage of participants from the Pharmacovigilance community. Conduct presentations, distribute information, meet with current and potential scientists, make a splash with new drug developments, and receive named recognition at this event. Renowned Speakers, the most recent techniques, developments, and the newest updates in Pharmacovigilance are Hallmarks of this Conference.

It gives us immense pleasure in welcoming you to the 17th Pharmacovigilance 2018. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Pharmacovigilance in 2020 - future horizons and efficiencies
- Updates towards of legislation, policies, systems, technology, communication strategies and best practice in PV
- Challenges for good pharmacovigilance practices for the generic industry. How to overcome them?
- Importance of signal management for the generic industries
- Importance of pharmacovigilance for the pharma industries in India
- Focusing on the monitoring process of safety of medicines in India
- Pharmacovigilance and risk management planning
- Marketing authorization for medicines that do not have RMP
- Discussing the key feature of benefit risk assessments from a regulatory perspective and how the patient is included in the discussion
- Forming fundamental basis of regulatory decision making through benefit-risk assessments
- How Brexit will impact pharmacovigilance in India
- Any adverse impact on the rules, regulations and product registrations
- Manual and medical devices reporting: Detecting and evaluating drug safety signals
- Monitoring safety of medicative products during product life cycle
- Automation/Data Processing/AI – Future of PV
- Adverse event case reporting with the help of AI automation
- Decreasing phase trials by implementing predictive analytics to impact patient safety
- Current regulatory framework and expectations for good pharmacovigilance practices
- Explanation on the GVP modules and newly revised GVP structures
- 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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"Excellent topics of PV covered. Good panellists and speakers. Good Venue and Facilities"

Pharmacovigilance Officer / Nonclinical Toxicology Expert, Ferrer Internacional

AGENDA AT A GLANCE

DAY ONE - 15th November 2018

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 Topic TBC

A. RAMKISHAN
Deputy Drugs Controller, DDC(I)
CDSCO

10:00 Topic TBC

Speaker TBC
APCER Life Sciences

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 DISCUSSION WITH EXPERTS: Importance of pharmacovigilance for the pharma industries in India

- Investigate latest progress associated to post-marketing pv and the practice of drug safety throughout clinical trials
- Focusing on the monitoring process of safety of medicines in India
- Employing hundreds qualified personnel to operate, analyse and take required actions to follow with international regulations
- Necessary actions on changing regulations/auditing and necessity on risk-based approach
- Educating students, interns and faculty responsible for PV cell in institutes (Govt. as well as private) through pharma experts
- Pre-authorization clinical studies to determine possible divergence with respect to reference and thus different safety profile in terms of nature, seriousness or incidence of adverse reactions
- Focusing on increasing the pharmacovigilance activity by working on risk-management for biosimilars
- PV Operations & Outsourcing – Current Landscape and Future Trends

Moderator:

PRASHANT BODHE
Director
CliniSearch

Panellists:

RAJENDRA SANGHAVI
Sr. Consulting Clinician & Chairman - Medical Committee
Indian Drug Manufacturers' Association (IDMA)

SRIRUPA DAS
Associate Director - Medical Affairs
Abbott

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

SUJAY KULKARNI
Senior Manager, Clinical Research and Pharmacovigilance
GSK

GURPREET SINGH
Global Head, Pharmacovigilance Operations
Novartis

11:30 Topic TBC

Speaker TBC
Syneos Health

12:00 Decreasing phase trials by implementing predictive analytics to impact patient safety

- Applying the use of analytical tools into big data to render more informative and authentic strategic decisions
- Shorten phase III trials and increasing approval process using RWE
- Changing the quality to positively impact patient results by understanding the disease characteristic and aiding patterns, increasing medicines submission and assisting in interpreting treatment outcomes for individual patients
- Gaining anticipated benefit and value from controlled studies by adapting PV departments into cross functional teams

12:30 - Networking luncheon

Afternoon Chair Person

PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

13:40 Topic TBC

DEEPA ARORA
Vice President- Pharmacovigilance & Global Head- Drug Safety & Risk Management
Lupin

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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

AGENDA AT A GLANCE

DAY ONE - 15th November 2018

14:10 DISCUSSION WITH EXPERTS: Manual and medical devices reporting: Detecting and evaluating drug safety signals

- Monitoring safety of medicative products during product life cycle.
- Discussing about early warnings, possible signals with consider to adverse drug reactions which was before unknown or unquantified
- Medicine authorization for marketing each year and how the accelerated numbers of persons consuming these medicines has lead an increase in numbers of adverse events accounted to manufacturers and to regulators
- Discussing the life cycle of drug safety signal including signal detection, signal prioritization and signal evaluation and if the evaluation of a drug safety signal creates a new adverse reaction, then how these phases of the signal's life cycle will lead to an update of the products.
- Different ways to signal detection including traditional methods and data mining methods?
- Approaching statistical and analytic methods to detect, prioritize and evaluate signals in an efficient and proactive manner

Moderator:

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

Panellists:

MAYUR PARMAR
Deputy Collector
Government Of Gujarat

ARUN BHATT
Consultant – Clinical Research & Development

SANJEEV MIGLANI
Founder and Director
AWINSA Life Sciences

PRADEEPA RAMAKRISHNA
Global Safety Physician/ Lead Surveillance Physician
AstraZeneca

PV & AI

14:50 Automation/Data Processing/AI – Future of PV

- Adverse event case reporting with the help of AI automation
- Patient centric pv/adverse events: How AI decrease time spent sifting?
- Focusing on important activities of pharmacovigilance by developing automation case processing into adverse event
- Working smarter and faster with reliable data at your fingertips through automation of PV processes

15:20 DISCUSSION WITH EXPERTS: Pharmacovigilance and risk management planning

- Address uniformity and differences in risk management design in the ICH regions and other jurisdictions
- Identify the differences between important identified risks and important potential risks
- Marketing authorisation for medicines that do not have RMP
- Discussing the standard scheme and contents of Indian RMP in context of a risk management system and risk evaluation and mitigation strategy
- Discuss primary and non-routine tools for handle product risks, how the potency of selected tool is evaluated, and points to focus for the modification, revision, or release of a given non-routine intervention
- Discussing the standard sector of the regulatory models for pv in the environment of risk management planning and on the realistic feature of coping biopharmaceutical product risks in the context of benefits and the healthcare delivery system

Moderator:

PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

Panellists:

MANOJ SWAMINATHAN
Chief Manager / Head - Global Pharmacovigilance Center
Piramal

JAMAL BAIG
Country Head - Pharmacovigilance
Merck Sharp & Dohme

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

NIDHI VAISH DAS
Drug Safety
Roche Pharmaceuticals

16:00 - Afternoon Tea/Coffee

REGULATORY

16:20 DISCUSSION WITH EXPERTS: Current regulatory framework and expectations for good pharmacovigilance practices

- Marketing authorisation bearers with a goal of publicizing single DHPC in state where numerous marketing authorisation bearers are focused
- Explanation on the GVP modules and newly revised GVP structures
- Distinct level of info and knowledge although sustaining the quality and consistency of the information
- Having the requisite quality of coordination and cooperation among the different parties involved in issuing safety communications

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"Good efforts, well organised, experienced speakers, current and concrete topics. Promises delivered"

Pharmacovigilance Manager, Cheplapharm Arzneimittel GmbH

DAY ONE - 15th November 2018

- Advantages of medicine including the relevancy info on the seriousness, severity, frequency, risk factors, time to onset, reversibility of potential adverse reactions and expected time to recovery
- Doubtless concern to safety factor especially while qualified parties are executing their evaluations

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

K. BANGARURAJAN
Joint Drugs Controller (INDIA)
CDSCO (HQ)

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

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

ALAP GANDHI
Head Medical Affairs
GSK

SAKHARAM GARALE
General Manager, Medical Affairs & Public Health
Mylan Laboratories

17:00 **- Chairperson's closing remarks and end of conference**

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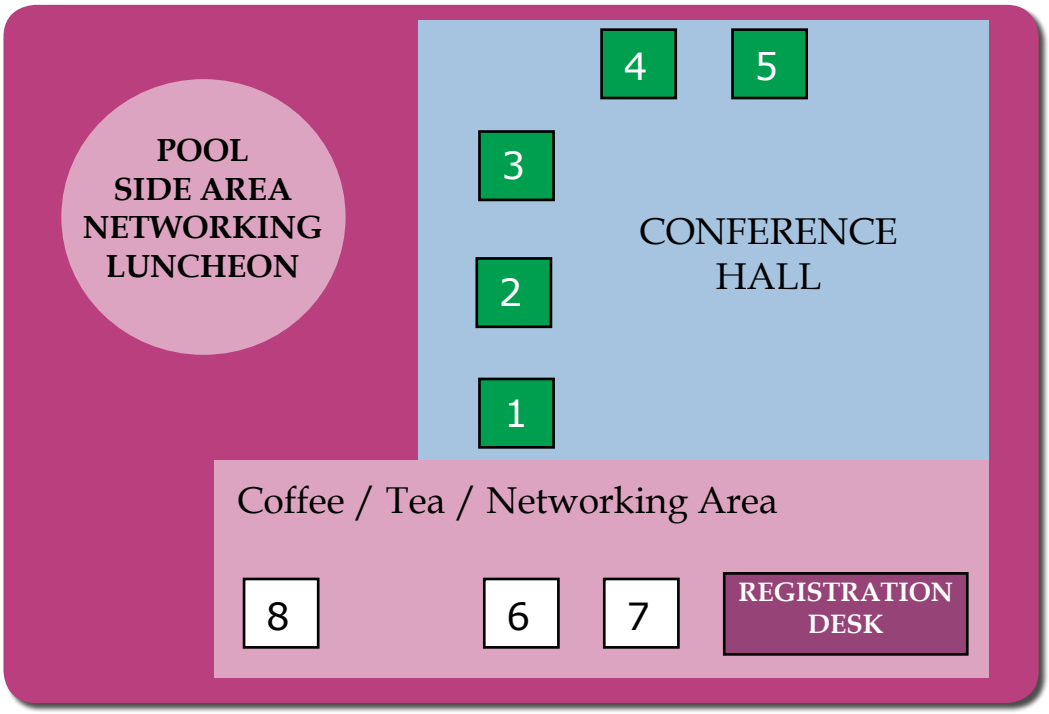
"The content of the conference is always good. Good to see speakers from regulatory authorities. Always delighted to attend your conference"

Medical Services, Cipla

AGENDA AT A GLANCE

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



1 APCER LIFE SCIENCES Together for better health

4 Med Vigil

7

2 Syneos Health

5 ELSEVIER

8

3 AB-Cube Making Safety Easy

6

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

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"It was very good conference. Thank you very much for offering me a speaker position. Keep up the good work and all the best for future conference"

Head Pharmacovigilance, Wockhardt

AGENDA AT A GLANCE

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 12th October 2018

1 day conference per delegate - Fee: INR 10,000 + GST(18%)

Standard Rate (13th October 2018 Onwards)

1 day conference per delegate - Fee: INR 15,000 + GST(18%)

For Bulk Booking of More Than 5 Delegates

Please email us at bookings@virtueinsight.com

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Company .....

GST No (If Applicable) .....

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Address .....

.....

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Email .....

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

Signature .....

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Account Type	- Current
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Bank Address	- 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
Branch Name	- Virugambakkam, Chennai
Swift Code	- AXISINBB211
NEFT / IFSC Code	- UTIB0000211
Micro Code	- 600211010

Queries:
Should you have any questions on bookings,
Please feel free to contact us.

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Web: http://www.virtueinsight.com
India Office: Tel: +91 44 42108101

General Information Venue:
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Mumbai 400059 - India
Tel: 91 22 66919000 / 91 22 28209999

Payment Terms:
Virtue Insight requires the full amount to be paid before the conference. Virtue Insight may refuse entry to delegates who have not paid their invoice in full.

Substitutions/name changes or cancellations:
There is a 50% liability on all bookings once made, whether by post, fax, or email. There is a no refund policy for cancellations received on or after one month before the start of the event. Should you decide to cancel after this date, the full invoice must be paid. Conference notes will then be sent to you. Unfortunately, we are unable to transfer places between conferences and executive briefings. However, if you cannot attend the conference, you may make a substitution/name change at any time, as long as we are informed in writing by email, fax or post. Name changes and substitutions must be from the same company or organization and are not transferable between countries.

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 refund your registration fee and we will try to 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.

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Virtue Insight's preferred method of communication is by email and phone. Please ensure that you complete the registration form in full so that we can contact you.

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VENUE

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MAP & DIRECTIONS

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"This conference is very useful for my work. I expect that every year Virtue Insight will organized this kind of conference"

Research Scientist, Alembic Pharmaceuticals Limited

UPCOMING CONFERENCES

UK

• (Pharma)	18th Pharmacovigilance 2019	27th & 28th February 2019, London, UK
• (Pharma)	Pharma Blockchain 2019	05th & 06th March 2019, London, UK
• (Pharma)	14th Biosimilars Congregation 2019	11th & 12th June 2019, London, UK
• (Pharma)	2nd Annual Pharma AI & IoT 2019	10th & 11th July 2019, London, UK
• (Pharma)	8th Annual Pharma AntiCounterfeiting & Serialisation 2019	16th & 17th July 2019, London, UK

USA

• (Pharma)	16th Pharmacovigilance 2018	02nd & 04th October 2018, Massachusetts (USA)
• (Pharma)	19th Pharmacovigilance 2019	09th & 10th October 2019, Chicago, USA
• (Pharma)	3rd Annual Pharma Pricing, Reimbursement & Market Access 2019	16th & 17th October 2019, Chicago, USA

INDIA

• (Pharma)	17th Pharmacovigilance 2018	15th November 2018, Mumbai, India
• (Tech)	11th Annual Cloud & Big Data Analytics 2018	29th November 2018, Bangalore, India
• (Pharma)	13th Biosimilars Congregation 2018	11th December 2018, Mumbai, India
• (Pharma)	2nd Annual Pharma Regulatory Summit 2019	14th March 2019, Mumbai, India
• (Tech)	Blockchain 2019	11th April 2019, Bangalore, India
• (Pharma)	10th Annual Clinical Trials Summit 2019	23rd May 2019, Mumbai, India
• (Tech)	6th IoT & AI Summit 2019	4th July 2019, Bangalore, India
• (Pharma)	2nd Annual Pharma Packaging, Labelling, Serialisation, Track and Trace 2019	19th September 2019, Mumbai, India
• (Pharma)	20th Pharmacovigilance 2019	07th November 2019, Mumbai, India
• (Pharma)	15th Biosimilars Congregation 2019	12th December 2019, Mumbai, India

For more info on these summits - Kindly contact us at -

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Virtue Insight:-

Virtue Insight equips business professionals around the world with the latest indepth industry knowledge and provides networking opportunities in the telecom, infrastructure and pharmaceutical industry. Our aim is to provide a platform to share knowledge and insights and provide our event attendees to network effectively and deliver maximum ROI by make new business alliances. We strive to produce high quality conferences which include the latest topics which are delivered by world class leaders of the industry.
Our motto is to offer our customers the expertise and connections for a profitable business. Our events encompass an optimum chance to gain maximum value in terms of networking and an opportunity to sponsor and exhibit to attract new business alliances.

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