

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



RUBINA BOSE
Deputy Drugs Controller(India)
CDSCO (WZ)



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



DEEPA ARORA
Director
CLINEXEL Life Sciences



UJWALA NAIK
Country Head-Pharmacovigilance
Johnson & Johnson



JAMAL BAIG
Country Head- Pharmacovigilance
Merck Sharp & Dohme



NARESH TONDARE
Senior Director - National Regulatory Affairs
Biocon



SHIVANI ACHARYA
Associate Director - Clinical Development &
Pharmacovigilance
Abbott



ARUN BHATT
Consultant - Clinical Research & Development



GURPREET SINGH
Global Head, External Relationship Management
Novartis



SRIRUPA DAS
Director - Medical Affairs
Abbott



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



CHIRAG TELI
Head of Medical Services
Alkem Laboratories



MANALI AGRAWAL
Head Regulatory Affairs
Bayer



DHANARAJ E
Pharmacovigilance Lead
Biocon



PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences



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



SOFI JOSEPH
Head of Regulatory Affairs and Pharmacovigilance
Serdia Pharmaceuticals



JYOTSNA PATWARDHAN
Head Development QA
Novartis



PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
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....

WHO ATTENDS?

30+
Speakers

70%
Decision
Makers

3+
Hours of
Networking

1
Day

1
Golden
Opportunity

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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

SILVER PARTNER



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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

MARKET OVERVIEW & ANALYSIS

09:30 / Pharmacovigilance and social media: An industry view

- Adverse drug reactions: a significant cost on society
- Pharmacovigilance a potentially intellectual reservoir of information
- Addressing a number of technical, regulatory and ethical challenges
- Presenting possible solutions by identifying relevant current research

10:00 / Traditional medicines and herbal of pharmacovigilance: Solutions and innovations

- Herbal medicines uses: Developing reliable information on safety
- Addressing the specific differences of medicinal herbs and required modification to the synthetic medicines
- Discussing on recommended uses and safe conditions along with scientific opinions on herbal substances and preparations
- Regulatory procedures for companies seeking to bring herbal medicinal products to the market

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:

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

GURPREET SINGH
Global Head, External Relationship Management
Novartis

UJWALA NAIK
Country Head-Pharmacovigilance
Johnson & Johnson

JAMAL BAIG
Country Head- Pharmacovigilance
Merck Sharp & Dohme

SRIRUPA DAS
Director - Medical Affairs
Abbott

DHANARAJ E
Pharmacovigilance Lead
Biocon

11:30 / 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:

DEEPA ARORA
Director
CLINEXEL Life Sciences

ARUN BHATT
Consultant - Clinical Research & Development

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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

JYOTSNA PATWARDHAN
Head Development QA
Novartis

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

12:10 / Pharmacovigilance Analytics: The hype of big data for pharmacovigilance

- Establishing the age of big data in pharmacovigilance
- Rapidly increasing scale of available health data
- Large data sets for individuals, disease registries, pharmacogenomics
- Discussing about strategies in order to put it to the best use in pharmacovigilance and ultimately public health

12:40 - 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
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

Panellists:

CHIRAG TELI
Head of Medical Services
Alkem Laboratories

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

15:10 - Afternoon Tea/Coffee

REGULATORY

15:30 / The current regulatory framework and its global impact

- Overview of Indian regulatory framework, including 2012 Indian pharmacovigilance legislation
- Implications for the global environment
- Inspections and penalties for non-compliance
- Practical applications of definitions

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:

Panellists:

RUBINA BOSE
Deputy Drugs Controller (India)
CDSO (WZ)

NARESH TONDARE
Senior Director - National Regulatory Affairs
Biocon

SHIVANI ACHARYA
Associate Director - Clinical Development & Pharmacovigilance
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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 - 7th November 2019

SOFI JOSEPH
Head of Regulatory Affairs and Pharmacovigilance
Serdia Pharmaceuticals

MANALI AGRAWAL
Head Regulatory Affairs
Bayer

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

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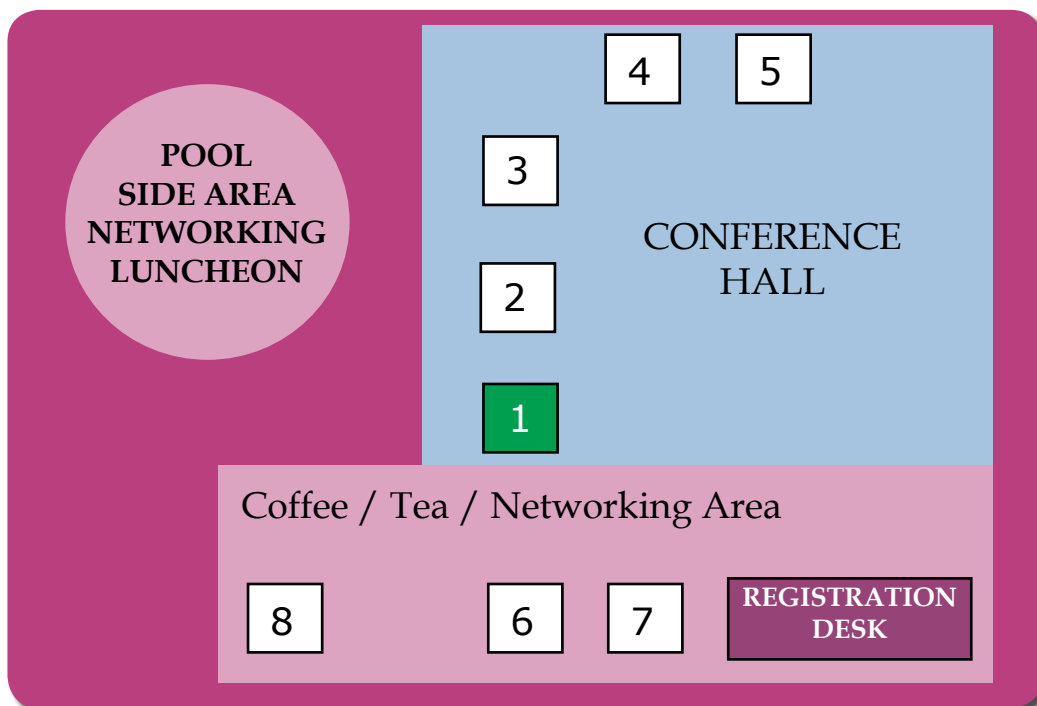
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“A great platform to understand the current practices & situation all across the industry, as well as individual approach of each company toward the goal of patient safety.”

Senior Executive, Lupin

AGENDA AT A GLANCE

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



1	 ELSEVIER	4	7
2		5	8
3		6	

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

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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

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 20th September 2019

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

Standard Rate (21st September 2019 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

Registration Form Details:

ForenameSurname

Job Title

Company

GST No (If Applicable)

Official Contact Number

Address

CountryPostcode.....

PhoneFax

Email

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

Signature

Methods of Payments:

By Cheque - Complete and return the above registration form via post or email, together with your cheque payable to Virtue Insight.

By Bank Transfer:

Account Name - Virtue Insight
Account Type - Current
Account Number - 915020031763553
Bank Name - Axis Bank
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.

Email: info@virtueinsight.com
Web: <http://www.virtueinsight.com>
India Office: Tel: +91 44 42108101

General Information Venue:

Kohinoor Continental Hotel
Andheri Kurla Road
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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.

How we will contact you:

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.

News Updates:

Please tick if you do not wish to receive email updates in the future

VENUE

Kohinoor Continental Hotel

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India.

Phone: 91 22 66919000 /
91 22 28209999



MAP & DIRECTIONS

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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

UPCOMING CONFERENCES

UK

• (Pharma)	8th Annual Pharma AntiCounterfeiting & Serialisation 2020	4th & 5th September 2020, London, UK
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USA

• (Pharma)	19th Pharmacovigilance 2019	8th - 10th October 2019, Chicago, USA
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INDIA

• (Pharma)	2nd Annual Pharma Packaging, Labelling, Serialisation, Track and Trace 2019	19th September 2019, Mumbai, India
• (Pharma)	20th Pharmacovigilance 2019	7th November 2019, Mumbai, India
• (Pharma)	14th Biosimilars Congregation 2019	12th December 2019, Mumbai, India

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

Phone - (India) - + 91 44 42108101 Email - (India) - info@virtueinsight.com

Phone - (UK) - + 44 - 2036120886 Email - (UK) - info.uk@virtueinsight.com

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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