3rd Annual Pharma Regulatory Summit 2020

"Understanding recent regulatory developments to explore innovative strategies"

12th March 2020, Kohinoor Continental Hotel, Mumbai, India

#VIpry

AGENDA AT A GLANCE

Key Speakers Include

RASHIDA NAJMI
Snr Vice President Global- Quality, Regulatory Pharmacovigilance and Patents, Piramal

SEEMA PAI
Director- India Cluster Global Site & Study Ops, Clinical Dev & Ops, GPD, Pfizer

KIRAN MARTHAK
Directors-Mgmt, Lambda(Vice Chairman of Medical Committee,Indian Drug Manufacturers' Association

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

V. KALAISELVAN
Principal Scientific Officer
Indian Pharmacopoeia Commission

PRASANNA BANGALE
Vice President & Head, Global Regulatory Affairs
Alembic Pharmaceuticals

MAHESH ABHYANKAR
Vice President - Medical and L and D
USV

ROHIT ARORA
Medical Director
Eli Lilly

ARUN GUPTA
Head Medical Affairs & Clinical Research
Dabur Research & Development Centre

ARIF KHAN
Head – Regulatory Affairs, Pharmacovigilance and Medical Information, UCB

AVINASH R. KAKADE
Pharmaceutical Physician Leader | Medical Doctor | Perpetual Learner | Mentor, Indian Institute of Management Rohtak

MANISH MAHAJAN
Head- Medical Affairs
Cadila Healthcare Ltd (BU- Biologics)

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

CHIRAG TELI
Head of Medical Services
Alkem Laboratories

ANISH DESAI
Director Medical Affairs,Clinical Ops. and Device safety, Johnson & Johnson

NARESH TONDARE
Senior Director - National Regulatory Affairs
Biocon

RAJESH KHER
Director, Business Operations, Regulatory Medical Writing, Janssen R&D

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"Good for getting knowledge & understand current requirements for Industry"

Sr. Executive – RA, USV

AGENDA AT A GLANCE

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

HITENDRA BHATIA
Manager Regulatory Affairs (Consumer Healthcare) Procter & Gamble Health

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser, Member Editorial Board Journal of Generic Medicines, England

PRATIK SHAH
(Former Head - Clinical, Medical & Regulatory, PV & QA Astellas),Independent Consultant

ACHARYA SESHU BABU MARINGANTI-
Business consultant, Former - Global Regulatory Operations, QA Operations, Abbott

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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MEDICAL EVENTS GUIDE

THE PHARMA TIMES.in www.thepharmatimes.in

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"This was one of the conference that I attended had many topics of high relevance and open environment for discussion."

Sr. Manager – Global RA, Abbott

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

India is an attractive target for pharmaceutical companies and other clinical research providers. India promises access to more patients, in greater concentrations, than most other markets, as well as the opportunity to establish trials with treatment-naïve patients. India is a pool of diverse population base of more than 1.2 billion and is a home for a numerous diseases, Institutions and hub of contract manufacturers and researchers. Indian economy stand as the third largest based on the Purchasing Power Parity (PPP) and in terms of globally eleventh largest by nominal Gross Domestic Product (GDP). India is today one of the top emerging markets in the global pharmaceutical scene. The sector is highly knowledge based and its steady growth is positively affecting the Indian economy. The organised nature of the Indian pharmaceutical industry is attracting several companies that are finding it viable to increase their operations in the country. Further, India is home to about 10,500 manufacturing units and over 3,000 pharma companies. India exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. These figures have given rise to legislation seeking to improve access to medicines and the Indian government has recently taken unprecedented steps to improve its healthcare and regulatory system

3rd Annual Pharma Regulatory Summit 2020 brings together leading global pharmaceutical industry professionals and regulators to share their insights on technologies, approaches, and solutions that will drive innovation and quality for the medicines delivered to patients worldwide. This interactive setting with expert-led regulatory and industry presentations and forums will ensure pharmaceutical industry professionals are well-prepared to develop and apply innovative solutions in today's global regulatory environment.

KEY THEMES DISCUSSED:-

- Understanding the current regulatory framework
- Overcoming key challenges with product registration in India
- Determining best strategies for the application and approval of variations in India
- Outlining key requirements for filing variations in India
- Current regulatory compliance issues and opportunities for regulatory authorities and industry experts
- Overviewing the current regulatory landscape in 2020 & 2021
- Clinical evidence for regulatory purposes
- Purpose of the public workshop. Bringing the team of investors together to discuss key issues for the use of randomized designs
- Exploring the current biosimilar legal landscape
- Studying the latest battles occurring in the biosimilar domain
- Developing scenarios for the Asian pharma market
- Top line innovation trends and implications
- The regulatory reform of India and its effect on the pharmaceutical industry
- Discussing the requisite collaboration between pharmaceutical companies and government agencies
- Digital regulatory innovation and advanced technology
- Insight into the future of regulatory issues in the digital world and how businesses need to adopt advanced technology to challenge the traditional way in which regulatory data and application processes are managed
- Practical guidance for drug registration compliance in India
- Navigating the best regulatory pathway for successful drug approval
- Be part of a major networking opportunity

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.

WHY EXHIBIT?

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

WHO SHOULD ATTEND AND WHO YOU'LL MEET: -

This conference is specifically designed for pharma, biotech, CRO's, Government and Regulators, Hospitals/Trial Sites, Technology & Solution Providers and medical device professionals responsible for:

Regulatory Affairs, Regulatory Writing/Medical Writing/Publishing/Information/Submissions, Document and eRecords Management, Business Operations/Processing, Labelling, Clinical Trials Management/Data, Clinical Data, Outsourcing/Clinical Outsourcing/Vendor Management, Product Development, Quality Assurance/Quality Control, Patient recruitment companies, Government- Department of health, Non-profit organizations/ Association, Consultants

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"Very good speakers and it was a good knowledge expansion. Arrangement was good."

Regulatory Affairs officer, Fresenius Kabi India

AGENDA AT A GLANCE

DAY ONE - 12th March 2020

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

09:20 – Chairperson opening remarks

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser
Member Editorial Board Journal of Generic Medicines, England

MARKET OVERVIEW & ANALYSIS

09:30 - Understanding the current regulatory framework

- Current regulatory environment and any recent changes
- Overcoming key challenges with product registration in India
- Best strategies for product registration
- Outlining major legal challenges currently being faced

10:00 - FDCs - Boon or Bane

- FDCs are flagship of India's formulations.
- Ridiculing FDCs sans sound medical basis will spell inconvenience for patients and compromise outcomes in chronic therapies.
- Differentiating between those justifiable and those scientifically irrational holds the key to future of FDCs.
- Governing rational FDCs prescribing is more a regulatory and a medical challenge rather than implicate the healthcare industry.
- Unbiased SOPs required to ensure necessary FDCs for patient's welfare.

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

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 - DISCUSSION WITH EXPERTS: Current regulatory compliance issues and opportunities for regulatory authorities and industry experts

- Overviewing the current regulatory landscape in 2020 & 2021
- How pharmaceutical companies stay ahead of these changes?
- How digital applications conflict with the legal and regulatory landscape?
- Clear specifications for registration and regulation of pharmaceutical products and medical devices in India
- Challenges in securing authorization from authorities for medical devices
- Regulations on trial guidelines, devices, safety, approval and market access
- Discussing strategies about global marketing campaigns for biosimilar products

Moderator:

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser
Member Editorial Board Journal of Generic Medicines, England

Panellists:

V. KALAISELVAN
Principal Scientific Officer
Indian Pharmacopoeia Commission

NARESH TONDARE
Senior Director - National Regulatory Affairs
Biocon

AVINASH R. KAKADE
Pharmaceutical Physician Leader | Medical Doctor Perpetual Learner | Mentor, Indian Institute of Management Rohtak

ACHARYA SESHU BABU MARINGANTI,
Business consultant, Former - Global Regulatory Operations, QA Operations & project management
Abbott

ROHIT ARORA
Medical Director
Eli Lilly

11:30 - DISCUSSION WITH EXPERTS: Clinical evidence for regulatory purposes

- Using randomized clinical trials for regulatory purpoes to generate real-world evidence
- Purpose of the public workshop. Bringing the team of investors together to discuss key issues for the use of randomized designs
- Explore key considerations for using randomized designs of clinical trials and real-world data (RWD) to generate RWE, especially in clinical care settings

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"Very well organised conference. Presentations was crisp and informative. Over all very knowledgeable."

Senior Manager, Sun Pharma Adavanced Research Center

AGENDA AT A GLANCE

DAY ONE - 12th March 2020

- Possible integration of clinical trials into the health care system through the use of randomized designs to generate RWE for regulatory applications
- Use of real-world evidence to support medical device regulatory decision-making
- Data collected from other sources, such as mobile devices, that can inform about health status

Moderator:

PRATIK SHAH
(Former Head - Clinical, Medical & Regulatory Affairs, PV and QA Astellas Pharma)

Panellists:

SEEMA PAI
Director- India Cluster Global Site & Study Operations, Clinical Development & Operations, GPD, Pfizer

ANISH DESAI
Director Medical Affairs, Clinical Ops. and Device safety
Johnson & Johnson

CHIRAG TELI
Head of Medical Services
Alkem Laboratories

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

12:10 - Topic TBC

ARIF KHAN
Head – Regulatory Affairs, Pharmacovigilance and Medical Information, UCB

12:40 - Networking luncheon

Afternoon Chair Person

13:50 – Topic TBC

MAHESH ABHYANKAR
Vice President - Medical and L and D
USV

14:20 – DISCUSSION WITH EXPERTS: Clinical Regulatory Medical Writing – Ensuring regulatory standards are met in structured and manageable timeline

- Regulatory medical writer: More than a writer, an expert
- Establish patient anonymization and de-identification processes that satisfy transparency requirements while preserving the integrity of the clinical research
- Increase the quality and speed of protocol writing by leveraging various templates, and minimize uncertainty in the interpretation of clinical data
- Analyze the benefits of having a medical writer as a strategic partner in document preparation and submission planning
- Create models for working with vendors/contractors that can be adapted for changing program and document needs
- Develop effective onboarding and mentoring programs that will allow you to recruit millennials and train the next generation of medical writers

Moderator:

Panellists:

RASHIDA NAJMI
Snr Vice President Global- Quality Regulatory, Pharmacovigilance and Patents, Piramal

KIRAN MARTHAK
Directors - Management, Lambda (Vice Chairman of the Medical Committee), Indian Drug Manufacturers' Association (IDMA)

RAJESH KHER
Director, Business Operations, Regulatory Medical Writing, Janssen R&D

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

15:10 – Afternoon Tea/Coffee

15:30 – Biosimilar and Healthcare Care Professionals: Need Gaps

- HCP perceptions of Biosimilars
- HCP views: Evidences on Biosimilars

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"Informative, got insights of current and fast changing scenarios."

Associate Regulatory Affairs, Abbot

DAY ONE - 12th March 2020

- Barriers and Facilitators to prescribe Biosimilars
- Patients perceptions to Biosimilars

MANISH MAHAJAN
Head- Medical Affairs
Cadila Healthcare (BU- Biologics)

.....

16:00 – DISCUSSION WITH EXPERTS: The Pharma Regulations in India: The Good, The Bad, The Ugly

- Pharmaceutical regulatory landscape in India
- Are regulations becoming strangulations for Pharma sector in India?
- Putting best foot forward with current regulations
- Pharma Regulatory Maize in India: Can there be winner?
- Navigating Regulatory Pathways to Address unmet medical needs
- Real World Evidence: Improve your regulatory intelligence for better business outcomes
- The Indian pharmaceutical industry – the way forward

Moderator:

Panellists:

PRASANNA BANGALE
Vice President & Head – Global Regulatory Affairs
Alembic Pharmaceuticalst

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

ARUN GUPTA
Head Medical Affairs & Clinical Research
Dabur Research & Development Centre

HITENDRA BHATIA
Manager Regulatory Affairs (Consumer Healthcare)
Procter & Gamble Health

.....

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

.....

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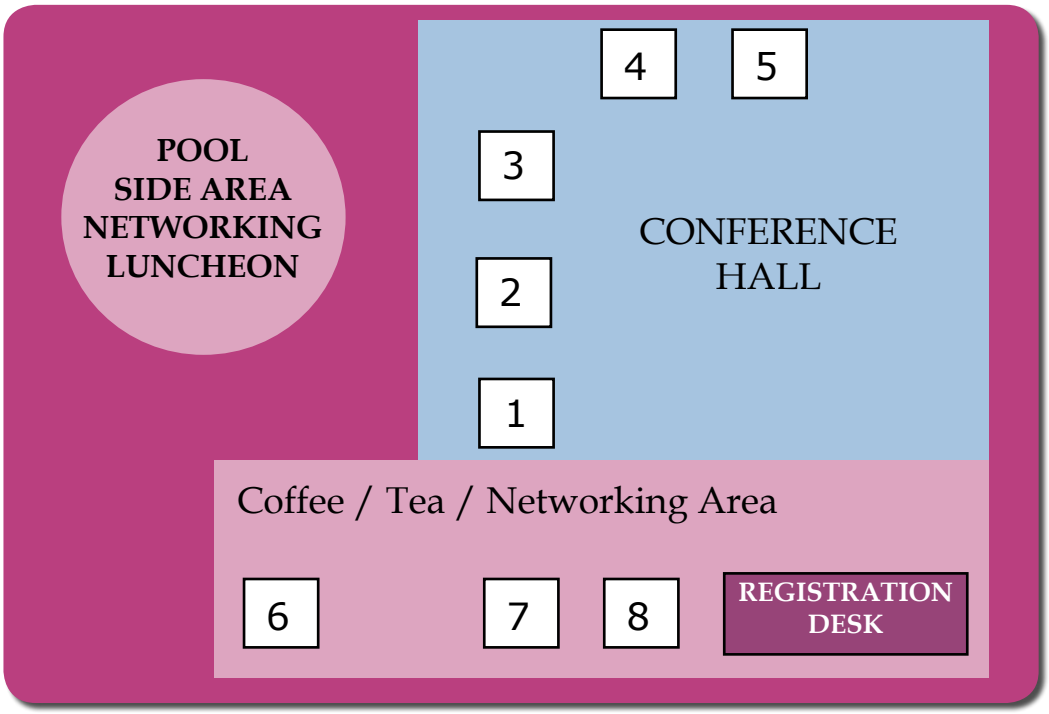
"Its a good conference covering all Corner of regulatory."

Sr. Scientist, Inventia Healthcare

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



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

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"The event has been organised very well, with a smooth flow of the full programme. Excellent selection of relevant topics and knowledgeable and expert presenters / Panelists."

Team Leader, Novo Nordisk

AGENDA AT A GLANCE

REGISTER ONLINE :

Link : https://www.bookmytrainings.com/catalogue/event/73612-3rd-annual-pharma-regulatory-summit-2020

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

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount

Cost per delegate (Valid till 24th Jan 2020) - Fee: INR 10,000 + GST(18%)

Standard Rate

Cost per delegate (Valid from 25th Jan 2020) - Fee: INR 15,000 + GST(18%)

Discounted Rate for Bulk Booking of More Than 5 Delegates

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

Registration Form Details:

Forename .....Surname .....

Job Title .....

Company .....

GST No (If Applicable) .....

Official Contact Number .....

Address .....

.....

Country .....Postcode.....

Phone .....Fax .....

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.

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General Information Venue:
Kohinoor Continental Hotel
Andheri Kurla Road
Andheri (E)
Mumbai 400059 - India
Tel: 91 22 66919000 / 91 22 28209999

TERMS AND CONDITIONS:

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.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of INR 5,000

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Presentation: If you cannot attend the conference, you can still purchase the presentations for INR 5,000 + Tax

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 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.

VENUE

Kohinoor Continental Hotel

Address: Andheri Kurla Road, Andheri (E), Mumbai - 400059, India.

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