2nd Annual Pharma Regulatory Summit 2019

"Understanding recent regulatory developments to explore innovative strategies"

#VIpry

14th March 2019,
Kohinoor Continental Hotel,
Mumbai, India

AGENDA AT A GLANCE

Key Speakers
Conference Info
Day One
Floor Plan
Booking Details
Upcoming Conferences

Key Speakers Include

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

V. KALAISELVAN
Principal Scientific Officer
Indian Pharmacopoeia Commission

KIRAN MARTHAK
Directors - Management, (Vice Chairman of the Medical Committee, IDMA)
Lambda

MAYUR PARMAR
Deputy Collector
Government Of Gujarat

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

SHANTANU MUKHERJEE
Legal Head, Asia Pacific and Japan
Lupin

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

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

SONIKA SHAH
Regulatory Affairs Head
Amgen

RAJESH NAIK
Head Medical Affairs Oncology
Boehringer Ingelheim

ALAP GANDHI
Head, Medical Affairs
GSK

RITU JOHARI
Head-Scientific Affairs, Quality & Regulatory
Abbott Diabetes Care

MILIND NARVEKAR
Head Regulatory Affairs
Apotex Research

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

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

VIJAYA ANAND
Chief Manager - Corporate Regulatory Affairs
Piramal

NISHA FERNANDES
Manager - Regulatory Affairs
Amgen

HITENDRA BHATIA
Independent Consultant – Regulatory Affairs

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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CONFERENCE locate.com

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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

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CONFERENCE INTRODUCTION:-

The 2nd Annual Pharma Regulatory Summit 2019 produced by Virtue Insight is the leading platform for regulatory experts, to be updated with latest country updates and strategies to navigate the complex and ever changing regulations in the region.

The pharmaceutical industry is a highly regulated industry. The regulatory requirements are permanently growing to ensure supply of high pharmaceutical quality, safety and efficacy of medicinal products. The factor time is now playing a more important role to allow expedited patient's access to innovative medicinal products to treat their disease and improve their life. This conference will focus on the new strategies, amendments, innovations, developments in the fields of regulatory affairs, intellectual property and medical devices, which reflects new strategies in the field of regulatory affairs. Regulatory Affairs additionally have certain significance inside the Healthcare industries, such as pharmaceuticals, medical devices, biologics and practical nourishments. The regulatory capacity in healthcare services is crucial in making secured and viable social insurance items accessible around the world. People who guarantee administrative consistence and prepare submissions, and additionally those whose primary occupation activity is clinical affairs or quality affirmation are altogether viewed as regulatory experts

Virtue Insight brings you it's 2nd Annual Pharma Regulatory Summit 2019 scheduled on 14th March in Mumbai, focusing on the clarification and interpretation to the most critical regulatory guidelines faced by the Indian Pharma companies.

It gives us immense pleasure in welcoming you to the 2nd Annual Pharma Regulatory Summit 2019

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Visions for the future – Pharma Regulatory 2020
- Current state of regulatory compliance in Pharma industry
- Global regulatory challenges and current hot topics in the regulatory world
- Conducting an innovative and commercialization hub in India
- Conception and Digitalisation – The impact and where do we go next?
- Directing the regulatory environment in India
- Expedited approval timelines and process - Overview and case studies
- Discussing on the recent harmonization regulatory efforts in Asia for the pharma products
- Companies & Gov – How should they work together?
- Different regulatory obligation for enrolling drug products for the regulatory process for obtaining marketing authorizations for drugs in ASEAN region
- Compendial standards usage for quality medicine regulation
- Post-Marketing surveillance & safety in India
- Post marketing monitoring and evaluation of the safety and effectiveness of all medicines
- Impacts and Opportunities for IP strategies in regulatory affairs – Globally & Digitally
- Future conceptualization for IP strategies and its regulatory significance
- An essential management aspect on GMPs
- Keeping tracks on GMP production and quality control
- Leading quality manufacturer in regulated industries including food, drugs and medical devices
- India's current regulatory scenario and structure – what's changed and what else to expect
- 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

This conference is specifically designed for pharma, biotech, CRO's, Government and Regulators, Hospitals/Trial Sites, Technology & Solution Providers and med 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

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

Regulatory Affairs officer, Fresenius Kabi India

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DAY ONE - 14th March 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 Topic TBC

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

10:00 Visions for the future – Pharma 2020

- Growth areas for drug pipeline
- Regulatory trends
- Market access and pricing point
- How should pharma industry respond in the most significant trends in the long term
- Companies and Gov – How should they work together?

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 DISCUSSION WITH EXPERTS: Directing the regulatory environment in India

- Expedited approval timelines and process - Overview and case studies
- What are the commonly-encountered challenges in drug approval processes - Discussing the regulatory pain points
- Issues while sourcing medical devices product approvals from authorities
- Challenges on new clinical trials regulation (536/2014) – A brief introduction
- Regulating operations for AI and future regulatory operation models globally. What are the new solutions?
- Present regulatory outlook developments for biologics and updates on registration & variation guidelines

Moderator:

SHANTANU MUKHERJEE
Legal Head, Asia Pacific and Japan
Lupin

Panellists:

V. KALAISELVAN
Principal Scientific Officer
Indian Pharmacopoeia Commission

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

ALAP GANDHI
Head, Medical Affairs
GSK

NISHA FERNANDES
Manager - Regulatory Affairs
Amgen

HITENDRA BHATIA
Independent Consultant – Regulatory Affairs

11:30 DISCUSSION WITH EXPERTS: Discussing on the recent harmonization regulatory efforts in Asia for the pharmaceutical products

- Different regulatory obligation for enrolling drug products for the regulatory process for obtaining marketing authorizations for drugs in ASEAN region
- Proactively address and avoid costly delays for product launch by evolving ad-hoc requests from reviewers
- What are the remaining country-specific requirements to be addressed for successful marketing authorization, while ICH and EMA guidelines are acceptable in most of the ASEAN countries
- Regulations expertise to help and direct the Asian regulatory systems to accomplish drug product registration, and way to expand Asian medical markets
- Evaluating regulation responsibility, and dismissing the need for duplicate studies to meet diverse regulation requirements, and supporting the drug companies more time and assets that can be used towards research and development of new drugs

Moderator:

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

Panellists:

SONIKA SHAH
Regulatory Affairs Head
Amgen

VIJAYA ANAND
Chief Manager - Corporate Regulatory Affairs
Piramal

12:10 Compendial standards usage for quality medicine regulation

- Generics and OTC drug regulation in Southeast Asia
- Compliant regulation variable from different international and national, ICH, WHO standards
- Challenges faced while dossier submission and technical variation for regulators
- Employing compendial measure in application to help regulators and industry players

12:40 - Networking luncheon

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

Senior Manager, Sun Pharma Adavanced Research Center

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DAY ONE - 14th March 2019

Afternoon Chair Person

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

13:50 Post-Marketing surveillance & safety in India

- Post-marketing conditions and changes across biologics, vaccines and generics
- PV and RMP submission requirements in vaccines post-marketing surveillance
- ASEAN Common Technical Document (ACTD) requirements in safety studies, in line with ICH standards
- Post marketing monitoring and evaluation of the safety and effectiveness of all medicines

14:20 DISCUSSION WITH EXPERTS: Impacts and Opportunities for IP strategies in regulatory affairs – Globally & Digitally

- What are the circumstances and influences on IP protection with the rise of digitalization, harmonization and internationalization?
- Future conceptualization for IP strategies and its regulatory significance
- Recognizing the diverse aspects of IP and influences by taking a regulatory strategic approach
- IP characteristic and their impact and the influence on regulatory strategies/key issues/patents/trademarks and copyright as well as data and market exclusivity for global pharmaceutical products
- Develop own IP policies, management style, schemes etc… depending on its area of specialty
- Assisting the economic growth of a country by supporting healthy competition and encouraging industrial advancement and economic growth.

Moderator:

Panellists:

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

MILIND NARVEKAR
Head Regulatory Affairs
Apotex Research

15:10 – Afternoon Tea/Coffee

15:30 India's current regulatory scenario and structure. What's change ,what else to expect.

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

16:00 DISCUSSION WITH EXPERTS: Leading quality manufacturer in regulated industries including food, drugs and medical devices

- Global regulatory challenges and current hot topics in the regulatory world
- Cooperating with the interphase of drug growth, manufacture, market and clinical research.
- Inputting regulatory principles on the development of new product, preparation till submission to the issuing regulatory bodies of health authorities
- Probable risks, concerns, and key points for successful adoption of electronic labelling
- GMP regulation in Asia – Expectation, and key differences – A quality and lifecycle management
- Regulating the safety and efficacy of products to protect the health of public
- India's current regulatory scenario and structure – what's changed and what else to expect

Moderator:

Panellists:

KIRAN MARTHAK
Directors - Management, (Vice Chairman of the Medical Committee, IDMA)
Lambda

MAYUR PARMAR
Deputy Collector
Government Of Gujarat

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

RAJESH NAIK
Head Medical Affairs Oncology
Boehringer Ingelheim

RITU JOHARI
Head-Scientific Affairs, Quality & Regulatory
Abbott Diabetes Care

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

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Sr. Scientist, Inventia Healthcare

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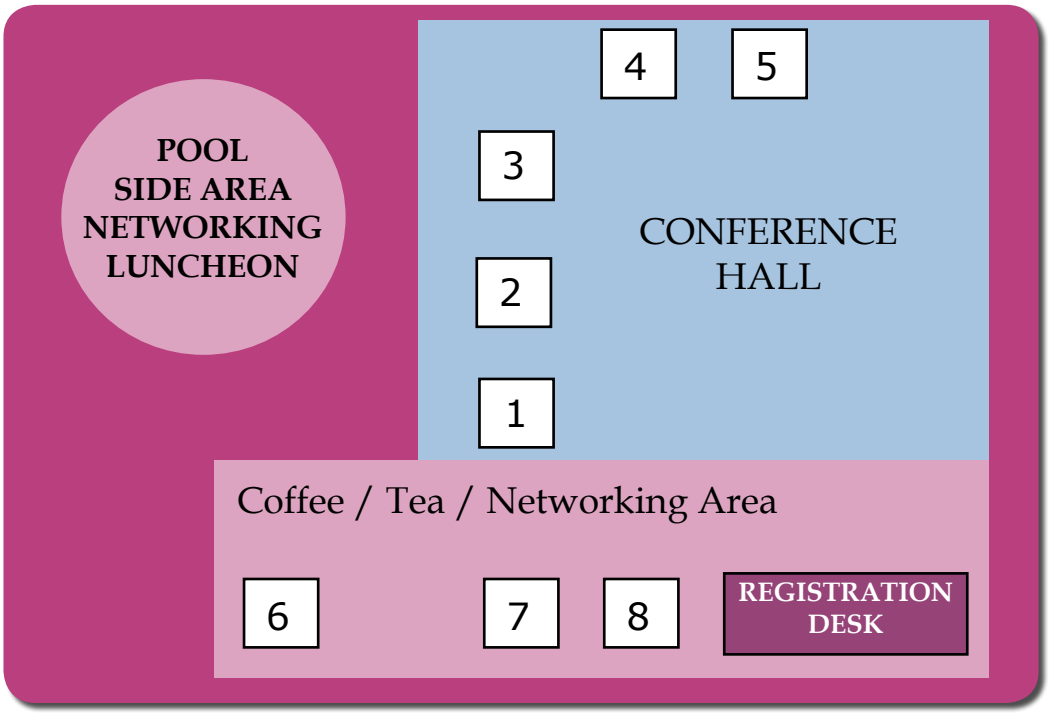
FLOOR PLAN - Book your stalls now before they run out !!!



1 4 7

2 5 8

3 6

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

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REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 28th January 2019

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

Standard Rate (29th January 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:

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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UK Office: Tel: +44 - 2036120886

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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Phone: 91 22 66919000 / 91 22 28209999

MAP & DIRECTIONS

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"Very well Organised and very nice content"

Deputy Collector, Government of Gujarat

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UPCOMING CONFERENCES

UK

• (Pharma)	18th Pharmacovigilance 2019	27th & 28th February 2019, London, UK
• (Pharma)	Pharma Blockchain 2019	05th & 06th March 2019, London, UK
• (Pharma)	13th 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)	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

• (Tech)	11th Annual Cloud & Big Data Analytics 2018	29th November 2018, Bangalore, 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 AI & IoT Summit 2019	3rd 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)	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

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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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