2nd Annual Pharma Regulatory Summit 2019

"Understanding recent regulatory developments to explore innovative strategies"

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

#VIpry

AGENDA AT A GLANCE

Key Speakers Include

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

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

MAYUR PARMAR
Deputy Collector
Government Of Gujarat

MUBARAK NAQVI
Medical Head of Insulins: Emerging Markets, Global Medical affairs
Sanofi

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

VISHAL MHATRE
Associate Vice President - Regulatory Affairs
Tata Consultancy Services

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

RITIKA GANJU
Partner
Phoenix Legal

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

ALAP GANDHI
Head, Medical Affairs
GSK

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

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

SAKHARAM GARALE
Head South-East Asia Operations ACMA

ASHWANI PANDITA
General Manager Quality Management & Training, Global Clinical Research Operations
Glenmark Pharmaceuticals

SALIL SAKSENA
GMP Consultant for FDA remediation with a MNC
ProClinical

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

JITENDRA KUMAR BADJATYA
Editor-In-Chief
International Journal of Drug Regulatory Affairs

PRALHAD TAYADE
GM Formulation Development R & D, Contract Research
Raptakos, Brett & Co.

UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics

VIJAYA ANAND
Chief Manager - Corporate Regulatory Affairs
Piramal

HITENDRA BHATIA
Manager Regulatory Affairs
Merck (A Procter & Gamble Company)

WHO ATTENDS?

30+ Speakers

70% Pharma / Biotech

3+ Hours of Networking

1 Day

1 Golden Opportunity

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

Sr. Executive – RA, USV

14th March 2019,
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AGENDA AT A GLANCE

PRINCIPAL PARTNER

Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

ASSOCIATE PARTNER

PHOENIX LEGAL

EXHIBITOR

Minitab | Qsutra

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THE PHARMA TIMES.in
www.thepharmatimes.in

INTERNATIONAL JOURNAL OF PHARMA AND BIO SCIENCES
ELSEVIER INDEXED JOURNAL

International Journal of Life science & Pharma Research
Thomson Reuters

Pharma Journalist

THE FREE PRESS JOURNAL

IJRA

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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

14th March 2019,
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Mumbai, India

AGENDA AT A GLANCE

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

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

AGENDA AT A GLANCE

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 Quality risk management in pharmaceuticals

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

10:00 Regulatory insights, related trends and use of automation in Reg operations

VISHAL MHATRE
Associate Vice President - Regulatory Affairs
Tata Consultancy Services

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:

MUBARAK NAQVI
Medical Head of Insulins: Emerging Markets, Global Medical affairs
Sanofi

Panellists:

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

SHIRAZ KANDAWALLA
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Head, Medical Affairs
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Merck (A Procter & Gamble Company)

UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics

RITIKA GANJU
Partner
Phoenix Legal

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:

VIJAYA ANAND
Chief Manager - Corporate Regulatory Affairs
Piramal

SAKHARAM GARALE
Head South-East Asia Operations ACMA

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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 - 14th March 2019

12:10 **Overview of regulation in India and CDSCO updates with specific reference to New Drug, Clinical trial, medical devices**

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

12:40 - Networking luncheon

Afternoon Chair Person

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

13:50 **Criteria to qualify as compassionate use**

- Patients suffering from life threatening diseases, or diseases causing serious permanent disability
- No comparable or satisfactory therapy available to diagnose, monitor, or treat the patient's disease or condition.
- That the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition.
- Sufficient evidence of the safety and effectiveness of the investigational product to support its use in the particular circumstance;
- Investigational product will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval
- The patient is unable to participate in a clinical trial.

SAKHARAM GARALE,
Head South-East Asia Operations ACMA

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:

SALIL SAKSENA
GMP Consultant for FDA remediation with a MNC
ProClinical

Panellists:

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

VISHAL MHATRE
Associate Vice President - Regulatory Affairs
Tata Consultancy Services

15:10 – Afternoon Tea/Coffee

15:30 **Visions for the future – Pharma 2020**

- Growth areas for drug pipeline
- Regulatory trends and expectation from Indian and International Regulatory Agencies
- Market access and pricing point
- Most significant strategy for long term sustainability
- Areas need Industry and Regulatory Agency collaboration

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

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:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

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

Associate Regulatory Affairs, Abbot

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DAY ONE - 14th March 2019

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Sr. Consulting Clinician & Chairman - Medical Committee
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Head Regulatory Affairs GDD India
Novartis

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Head-Scientific Affairs, Quality & Regulatory
Abbott Diabetes Care

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

ASHWANI PANDITA
General Manager Quality Management & Training, Global Clinical Research Operations
Glenmark Pharmaceuticals

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

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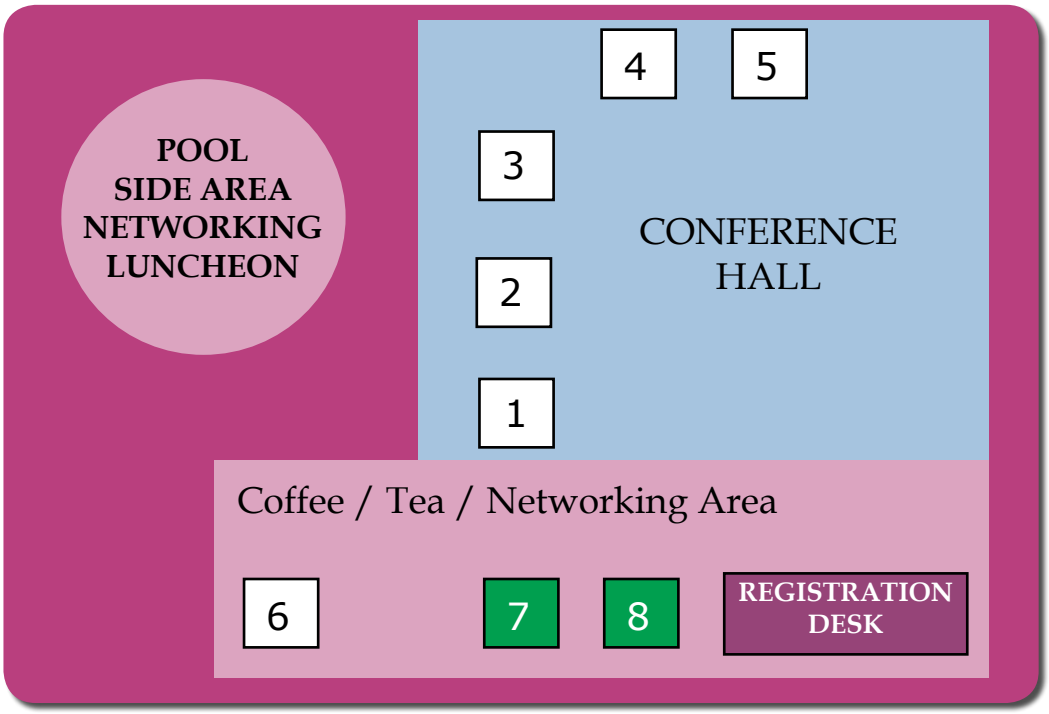
AGENDA AT A GLANCE

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



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7 DDi Smarter Technology

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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

REGISTRATION FORM

RESERVATION PRICING:

Standard Rate

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 .....

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

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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
UK Office: Tel: +44 - 2036120886

General Information Venue:
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Tel: 91 22 66919000 / 91 22 28209999

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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.

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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.

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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.

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

VENUE

Kohinoor Continental Hotel

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MAP & DIRECTIONS

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Deputy Collector, Government of Gujarat

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UPCOMING CONFERENCES

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	08th - 10th October 2019, Chicago, USA
• (Pharma)	3rd Annual Pharma Pricing, Reimbursement & Market Access 2019	16th & 17th October 2019, Chicago, USA

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 Annual IoT & AI 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 -

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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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