Pharma Regulatory 2018

"Understanding recent regulatory developments to explore innovative strategies"

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

#VIpry

AGENDA AT A GLANCE

Key Speakers Include

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

DEBOLINA PARTAP
Vice President Legal & GC
Wockhardt

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

PRASHANT DESAI
Director – Regulatory Affairs & Business Quality
Johnson & Johnson

VAIBHAV KULKARNI
Director - Regulatory Affairs
Abbott Nutrition

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-Aventis

SRIRUPA DAS
Associate Director - Medical Affairs
Abbott

NAVEEN KUMAR NAGARAJA
Assistant Director Regulatory Affairs
Takeda

SHANTANU MUKHERJEE
Legal Head, Asia Pacific and Japan
Lupin

KEDAR SUVARNAPATHAKI
Head - Regulatory Affairs & IP
Boehringer Ingelheim

SANJAY KUMAR
Head of Legal Ethics & Compliance
GSK Consumer Healthcare R&D India

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

NARESH TONDARE
Head – India and Nepal Regulatory Affairs
Glenmark Pharmaceuticals

SONIKA SHAH
Regulatory Affairs Head
Amgen

QAYUM MUKADDAM
Independent Consultant
(Former Head- Medical & Regulatory Affairs - Galderma India)

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

ALAP GANDHI
Head, Medical Affairs
GSK

RANJIT BARSHIKAR
QbD / CGMP Consulting
Editorial Member of Journal of Generic Medicine – England

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

Plus many more COMING SOON.....

WHO ATTENDS?

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

www.virtueinsight.com

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Plot No – 07 – 2nd Floor
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"New topic to organize by virtue insight appreciate your choice of current hot topics participated as a deligate with inquisitiveness to learn more biosimilars mission accomplished"

HEAD PV, BMS INDIA

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

Virtue Insight is proud to announce its first Pharma Regulatory 2018 conference.
This unique event will bring key stakeholders gather with the aim of promoting and undertaking to continue work towards a more efficient pharma regulatory system. In the spirit of constructive cooperation, this event brings together representatives from the industry and regulators as well as healthcare professionals.

In order to succeed in this new environment, it is critical to be up to date on regulatory hurdles and be transparent in all regulatory process. The summit features government and regulatory authorities and expert insights to help you tackle and overcome these regulatory challenges, and to improve the drug and device approval processes for pharmaceutical, biopharmaceutical and medical device companies.

Virtue Insight brings you it's first Pharma Regulatory 2018 scheduled on 15th March in Mumbai, focusing on the clarification and interpretation to the most critical regulatory guidelines faced by the Indian Pharma companies. This one day strategical summit provides insights on the US, Europe and ROW region which presents the major revenue of the top Indian pharmaceutical companies

It gives us immense pleasure in welcoming you to the Pharma Regulatory 2018

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Registration, Compliance and Approval – What next?
- Uncommon diseases: Scientific and regulatory challenges worldwide
- Product registration and current regulatory intels: Challenges and opportunities
- Regional government updates on initiatives, cutting backlogs, current guidelines
- Regulatory landscape: With data in the global regulatory and pharmaceutical surroundings what challenges and opportunities arises
- Evaluating the regulatory anticipations, opportunities and challenges for biosimilar orphan drugs
- Drug approval blockades - And how to operate with regulators to optimize timelines
- Investigating the regulatory surroundings for biosimilars in India
- The challenges of the Indian Regulation – How to adapt and when?
- Pharmacovigilance Regulations - REMS vs RMP, PSUR Submissions, and other updates
- Deciding better schemes for registering a variation and gaining approval in India
- Comprehensive views on OTC product registration, License, Compliance, Safety and Risk Control
- Cutting down the backlog of Clinical Trial and Marketing Applications – Clinical Trial Application (CTA) procedure and its timeline
- Patient information booklet and labeling ways in Asia – How regulation analyses it?
- Supply chain, Labelling and Distribution - Standards and cooperative strategies needed
- 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

SUPPORTED BY

WITNESS – India's First Magazine on Legal and Corporate Affairs – www.witnesslive.in
GoingToMeet – Where Business and People Converge
Conference Locate.com
bookmytrainings.com – India's No.1 Training Marketplace
EXPLARA

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"A commercial knowledge venture explored several areas under the topic. Very good and Professional speakers. Over all more than satisfaction"

Director, SYNORBS BIOSOLUTIONS

AGENDA AT A GLANCE

DAY ONE - 15th March 2018

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 Evaluating the regulatory anticipations, opportunities and challenges for biosimilar orphan drugs

- Comparative clinical studies for biosimilar orphan drugs – Expectations of regulatory authority
- Determining whether full-scale comparative clinical studies are always feasible
- Surviving challenges considering determined populations and eminent costs of reference biopharmaceuticals
- Biosimilar orphan drugs on the market - Outlining future opportunities and challenges

10:00 Investigating the regulatory surroundings for biosimilars in India

- Analysing Indian content and necessities for biosimilars to Europe and the US
- Explaining whether the Indian counsel favours local companies and overcoming this hurdle
- Considering how to work efficaciously with, and which questions to ask local associates in India
- Researching how the market for biosimilars in India equates to the market for new entities
- Outlining key challenges in the Indian guidance and how these can be overcome
- Surviving regulatory CMC hurdles for developing biosimilars

10:30 - Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 DISCUSSION WITH EXPERTS: Registration, Compliance and Approval – What next?

- Best strategies for product registration
- Developing a product that meets authority's requirement
- Setting up the products in Asia – meeting regulatory and compliance requirements
- Good Submission Practice guideline for applicants
- Challenges in obtaining medical device product approvals from authorities
- Regulatory Priorities and New Initiatives
- Ideas for reducing drug approval timelines and back logs

Moderator :

Panellist :

ALAP GANDHI
Head, Medical Affairs
GSK

SRIRUPA DAS
Associate Director - Medical Affairs
Abbott

QAYUM MUKADDAM,
Independent Consultant
(Former Head- Medical & Regulatory Affairs - Galderma India)

11:30 DISCUSSION WITH EXPERTS: Uncommon diseases: Scientific and regulatory challenges worldwide

- Dealing the strategic views, experiences and learning's with regards to regulatory model for orphan drugs
- Challenges faced in emerging markets
- Communicating the experience from development process of medicines
- Analysing the possibilities provided by the different legislations for treatment of uncommon diseases
- Outlining the regulatory aspects that may impact approval of orphan drugs
- Drug approval blockades - And how to operate with regulators to optimize timelines
- Useful regulatory cooperation plans and a wish list for government intervention
- Approval process for orphan drugs in US/ EU

Moderator :

RANJIT BARSHIKAR
QbD / CGMP Consulting
Editorial Member of Journal of Generic Medicine — England

Panellist :

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

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

12:10 Deciding better schemes for registering a variation and gaining approval in India

- Describe key requirements for registering variations in India
- Explaining the assortment of variations and whether this is agreed across countries in India
- Exploring the timelines to get approval for variations
- Surviving the key objects related with filing variations in India

12:40 - Networking luncheon

Afternoon Chair Person

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"Very well organized and the sessions were so well placed. Got enough time for networking and well time managed"

Country Safety Lead, Pfizer Limited

AGENDA AT A GLANCE

DAY ONE - 15th March 2018

13:40 Clinical research- recent positive regulatory scenario

AMITA BHAVE
Head Regulatory Affairs GDD India
Novartis

14:10 PANEL DISCUSSION WITH EXPERTS: Product registration and current regulatory intels: Challenges and opportunities

- Looking into new and future changes to the regulatory area
- Describing how changes to regulatory demands are affecting industry
- Analysing precisely what is needed for submissions, variations and renewals
- Surviving tight deadlines for compliance with local pharmacopeia
- Analyzing whether to tend more towards Europe or US like needs
- Regional government updates on initiatives, cutting backlogs, current guidelines
- Noncompliance directions and how industry can develop

Moderator :

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

Panellist :

NARESH TONDARE
Head – India and Nepal Regulatory Affairs
Glenmark Pharmaceuticals

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Assistant Director Regulatory Affairs
Takeda

VAIBHAV KULKARNI
Director - Regulatory Affairs
Abbott Nutrition

14:50 Adapt or Perish: Big Pharma in 2017

- Challenging times for global Big Pharma: patent cliffs, pricing pressure and generic competition
- The GDUFA Legacy
- Growth: beg, buy, borrow/in-license, steal
- 'Masala' M&A: Indian companies, global ambitions

SHANTANU MUKHERJEE
Legal Head, Asia Pacific and Japan
Lupin

15:20 Patient information booklet and labeling ways in Asia – How regulation analyses it?

- News on patient leaflet and labelling in market
- Is there any potential of patient labelling required in many markets in Asia, and regulation surrounded it
- Preparing lay terms - challenge and solutions
- Supply chain, Labelling and Distribution - Standards and cooperative strategies needed
- What industry can expect after regulations changes on labelling?

15:50 – Afternoon Tea/Coffee

REGULATORY

16:20 DISCUSSION WITH EXPERTS: Regulatory landscape: With data in the global regulatory and pharmaceutical surroundings what challenges and opportunities arises

- Overview on current regulatory landscape
- Developing progressive technologies as it applies to regulatory science/technology and pharmaceutical society
- Adapting to revolutionary and developing technology (e.g.digital transformation). What are the challenges?
- Regulatory growths to endure digitization of pharma - Solving the drivers of risk and complication of legal consequences when digitisation arises
- Anticipation from government authorities - How is pharma operating around this?

Moderator:

Panellist:

SANJAY KUMAR
Head of Legal Ethics & Compliance
GSK Consumer Healthcare R&D India

DEBOLINA PARTAP
Vice President Legal & GC
Wockhardt

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-Aventis

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

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

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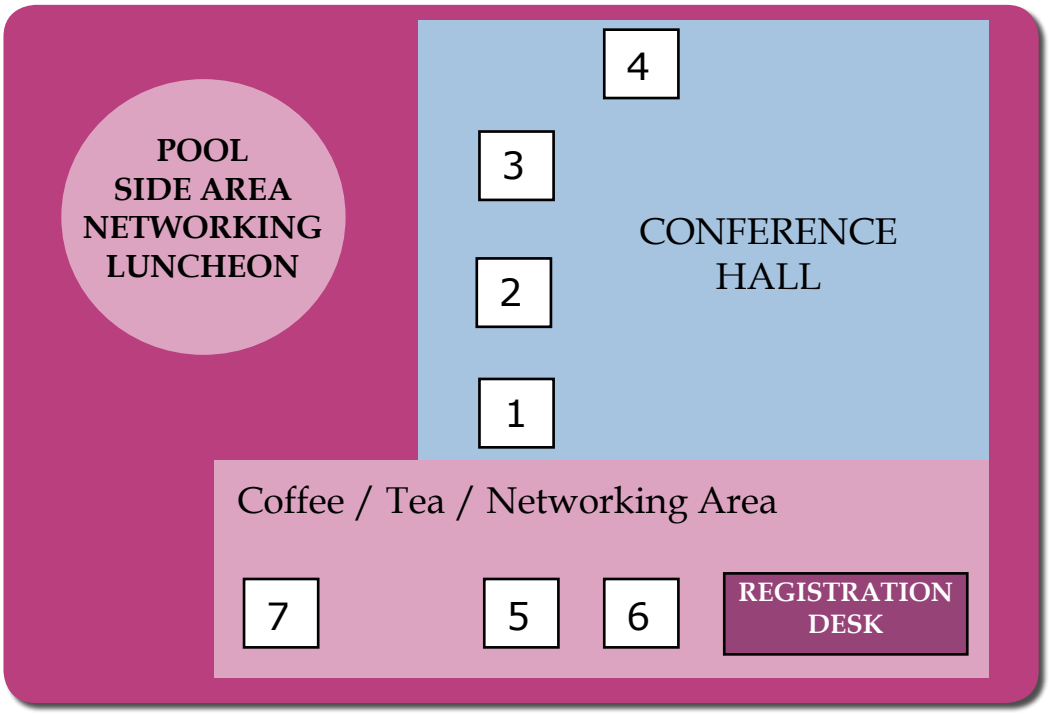
"A very good platform where cream of the Pharmacovigilance field of Indian pharma shared their views/opinions on involving of Pharmacovigilance trends & how to improve pv in India"

Business Development Associate, Techsol Systems India Pvt Ltd

AGENDA AT A GLANCE

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 conference was interesting and was a good platform for networking. The audience and the panelists were from varying backgrounds giving an insight to various challenges being faced by the Indian industry"

Manager- BD, ELC Research

AGENDA AT A GLANCE

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 28th January 2018

1 day conference per delegate - Fee: INR 6,000 + GST(18%)

Standard Rate (29th January 2018 Onwards)

1 or 2 delegates - per delegate - Fee: INR 7,000 + GST(18%)

Group Discounts

3 or 4 delegates - per delegate - Fee: INR 6,500 + GST(18%)

Group Discounts

For 5 & above delegates - per delegate - Fee: INR 6,000 + GST(18%)

Spot Registration:-

1 day conference per delegate - Fee: INR 8,000 + GST(18%)

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 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 64536444

General Information Venue:
Kohinoor Continental Hotel
Andheri Kurla Road
Andheri (E)
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

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

Phone: 91 22 66919000 / 91 22 28209999

MAP & DIRECTIONS

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"The conference was indeed a great experience.Both the presentations and the panel discussions/interactive sessions were very enlightening.I would surely like to attend the May clinical trial conference. I congratulate Virtue Insight for organizing a very useful and interesting Conference."

Medical Department, Elder Pharmaceuticals

AGENDA AT A GLANCE

UPCOMING CONFERENCES

- **15th Pharmacovigilance 2018 - 21st - 22nd February 2018, London, UK**
- **12th Biosimilars Congregation 2018 - 27th - 28th February 2018, London, UK**
- **Pharma Regulatory 2018 - 15th March 2018, Mumbai, India**
- **11th Annual Cloud & Big Data Analytics 2018 - 05th April 2018, Bangalore, India**
- **9th Annual Clinical Trials Summit 2018 - 24th May 2018, Mumbai, India**
- **Pharma AI & IoT 2018 - 13th - 14th June 2018, London, UK**
- **5th IoT & AI Summit 2018 - 05th July 2018, Bangalore, India**
- **7th Annual Pharma AntiCounterfeiting & Serialisation 2018 - 12th - 13th September 2018, London, UK**
- **Pharma Packaging and Labelling 2018 - 19th September 2018, Mumbai, India**
- **16th Pharmacovigilance 2018 - 27th - 28th September 2018, Chicago, USA**
- **3rd Annual Pharma Pricing, Reimbursement & Market Access 2018 - 14th - 15th November 2018, London, UK**
- **17th Pharmacovigilance 2018 - 15th November 2018, Mumbai, India**
- **13th Biosimilars Congregation 2018 - 13th December 2018, Mumbai, India**

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

Phone - (India) - + 91 44 64536444
Phone - (UK) - + 44 - 2036120886

Email - (India) - info@virtueinsight.com
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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