

5th Annual Pharma Regulatory Summit 2022

#VIpry

"Understanding recent regulatory developments to explore innovative strategies"

09th & 10th March 2022, Virtual Conference (Time Zone - IST)

AGENDA AT A GLANCE

Key Speakers
Conference Info
Day One
Day Two
Booking Details

Key Speakers Include



K BANGARURAJAN
Adviser
CDSCO (New Delhi)



MAYUR PARMAR
Deputy Collector
Government of Gujarat



RAJENDRA SANGHAVI
Sr. Consulting Clinician & Medico-Marketing
& TechnoRegulatory Consultant - Healthcare
Industry & Chairman - Nutraceutical
Committee, **Indian Drug Manufacturers'**
Association (IDMA)



RASHMI HEGDE
Executive Vice President Medical Affairs
GSK



PRASANNA BANGALE
Vice President and Head, Global Regulatory
Affairs, **Alembic Pharmaceuticals**



PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines



OMPRAKASH S. SADHWANI
Former Joint Commissioner and Controlling
Authority **FDA (Maharashtra state)**



NAVANEETHA SELVAN
Associate Vice President - Global Regulatory
Affairs, **Wockhardt**



SANJAY SHARMA
Vice President Technology Transfer
Lupin



TAUSIF AHMED
VP & Head Biopharmaceuticals & Bioanalytical
Global Clinical Management
Dr. Reddy's Laboratories



SAILAJA SAYANA
Senior Director & Head - Global
Pharmacovigilance, **Biocon**



AMIT BHARGAVA
Director
H.E.A.R.T of Medicine (Former VP, Lupin)



MANISH MISTRY
Medical Director
Novartis



VAIBHAV CHOUDHARY
Joint Director, Medical and Clinical Affairs
Fresenius Kabi Oncology



RAJESH KHER
Director, Business Operations, Regulatory
Medical Writing, **Janssen**



ANUP CHOUDHURY
Associate Medical Director, Clinical
Development, **Novartis**



ANJU AGARWAL
Director Global Patient Safety
Advanz Pharma



KRANTHI KIRAN PEBBILI
Director and Cluster Head - Medical Affairs
Dr. Reddy's Laboratories



RISHI JAIN
Medical Director
AbbVie



SUMIT SANT
Director, Clinical Safety, Global Product Safety
and Risk Management, **Viatrix**

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SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott



AMEY MANE
Director Medical Affairs
Dr. Reddy's Laboratories



MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates



PRAVEEN KUMAR L
Director - Regulatory Affairs
Cipla



KUMAR GAURAV
Director Medical Affairs
Dr. Reddy's Laboratories



YATEEN SHAH
Director - Regulatory Affairs & Quality
Johnson & Johnson



KAVITA LAMROR
Director, Real World Investigator, Digital
Function, **Sanofi**



SOFI JOSEPH
Regulatory Affairs & Pharmacovigilance
Director, **Serdia Pharmaceuticals**



DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories



SUMIT ANAND
Associate Director Clinical Operations
Abbott



VIPUL JAIN
Associate Director - SCM Integrated Business
Planning, **Cipla**



SHAHU INGOLE
General Manager, Head Medical Affairs
Wockhardt



MANGALA KOTNIS
Head Regional Medical Affairs
Abbott



VAIBHAV SALVI
Head - Medical Information, Asia
Sanofi



VICKRAM SRIVASTAVA
Head of Planning - Global Supply Chain
Sun Pharma



SADANAND KULKARNI
Head-Medical, Regulatory, Vigilance, Quality
Fresenius Kabi



VISHWAS SOVANI
Founder Director
Pharmawisdom



VARSHA KHATRY
Head Medical and Scientific Affairs, Quality
and Regulatory, **Roche**



VIPIN SETHI
Global Pharmacovigilance Head - Medical
Affairs, **Cadila**



GEETA SHANBHAG
Sr. General Manager - Pharmacovigilance &
Medico-Regulatory Affairs, **Ipca Laboratories**

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RAJENDRA JANI
Senior Subject Expert & Advisor
Clinical Research Consultant



INDRANIL PURKAIT
General Manager and Head Medical Affairs
Ipca Laboratories



SANJIV DONWALKAR
Head - Operational Excellence
Novartis



MANJIRI WARANG
Medical Writing - Clinical Development
Sun Pharma



NEHA VALA
Head- Pharmacovigilance
Emcure Pharmaceuticals

Plus more COMING SOON.....



ASHWANI PANDITA
General Manager - Clinical Quality
Management & Training, Glenmark



RAVI GAWARE
Head of Clinical Operations
Novo Nordisk



GANESH KADHE
Senior Leadership Team Member, Scientific &
Medical Affairs, Abbott Nutrition



APARNA PRABHUNE
Asst General Manager Regulatory Affairs
Wockhardt



SUDIPTO BASU
Senior Manager - Demand Planning
Boehringer Ingelheim

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CONFERENCE INTRODUCTION

In the pharmaceutical sector specifically, the global regulatory affairs outsourcing market is expected to be worth \$14.3 billion by 2026, a CAGR of 12%.¹ Meanwhile, the whole medical device outsourcing market is expected to be worth over 230 billion by 2027. There is clearly a growing trend for quality, compliance and regulatory outsourcing and it is likely to be accelerated by the healthcare crisis. The Indian Pharmaceutical industry is expected to grow to USD 100 billion by the end of 2025. Pharmaceuticals exports from India stood at USD 16.3 Billion in FY 2019-20. The Indian biotechnology industries was valued at US\$ 64 billion in 2019 and is expected to reach US\$ 150 billion by 2025.

India is the 4th largest market of medical devices in Asia and counted amongst the top 20 markets in the world. In 2020, the total market was estimated to be US\$5.2 billion and is projected to reach US\$50 billion by 2025. This high import dependency offers an attractive proposition for domestic manufacturers. At present, the Indian companies are largely involved in manufacturing low-end products for local as well as international consumption. The Indian Pharma market is the third largest in terms of volume and 13th largest in terms of value and 20 per cent in the volume.

Today Indian Pharma Sector can be attributed to world-class capabilities in formulation, the entrepreneurial skill and the vision of the industry to establish India's footprint in large international markets such as the United States, Canada, Europe and Japan. The US market, which accounts for a third of India's Pharma exports, recording over 14.5% growth over last fiscal.

Join us to discuss multi-regional cooperation, global harmonization and best practices related to India's regulatory landscape. Sessions will highlight regulatory approaches and good practices to ensure certainty in India and strategic initiatives to improve collaboration and cooperation.

KEY THEMES DISCUSSED

- The new normal for clinical development regulatory practices - Staying ahead of regulatory changes
- New EU CTR (536/2014) - being implemented in Jan 2022 and proposed draft IND safety reporting guidance from US FDA
- Lessons to learn from Covid pandemic - Potential benefits and risks of regulatory flexibility Striking the balance
- Present regulatory system for growth and effective production of medicinal products
- New regulations in Pharmacovigilance and the way forward
- The role of technology within regulatory compliance
- Prioritizing patient safety regulations
- Discussing how to ensure operational performance in compliance with the aim of better regulation
- New changes in Drug Supply Chain Security Act (DSCSA).
- Recent developments in GCP. How to succeed with this?
- Usage of mobile apps and medical devices in clinical trials - regulatory challenges
- RWE implementation in clinical trials. What are the challenges, chances and curses?
- Moving to electronic package-level traceability system - steps and barriers.
- Regulatory issues and maintaining quality in medical writing.
- Regulatory environment for medical devices in India as per 'New Medical Devices Rules'?
- Relationship between regulatory and technology in medical devices? A better understanding.
- What are the critical regulatory aspects for biotech companies? What should they look out for?
- Biosimilars market regulation, what are the benefits and drawbacks?
- Understanding the CGMPs under post pandemic. What changes will take place in priorities?
- Effective plans to maintain manufacturing and packing drug product methods under CGMPs?
- Ways to improve the combination of quality, safety and effectiveness in manufacturing.
- Be part of a both (together and one) virtual networking opportunity

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 e-Records 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.

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.

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DAY ONE - 09th MARCH 2022

09:20 - Welcome Address & Virtual Conference Platform Instructions

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09:30 - New EU CTR (536/2014) - being implemented in Jan 2022 and proposed draft IND safety reporting guidance from US FDA

SUMIT SANT

Director, Clinical Safety, Global Product Safety and Risk Management, **Viatrix**

.....

10:10 - Staying ahead of regulatory changes

- Don't forget SOP's
- Enabling companies to be practical in monitoring regulatory changes
- Need for a vital system of regulatory intelligence
- Successful management of a global QMS
- Recent regulatory changes in new drug submission
- What are digital standard operating procedures?

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10:50 - Morning Coffee/Tea & Discussion

.....

LESSONS FROM PANDEMIC

11:10 - DISCUSSION WITH EXPERTS: Potential benefits and risks of regulatory flexibility - Striking the balance

- How the COVID-19 pandemic has forced regulatory processes to adapt and focusing on the regulatory flexibilities
- Expedited reviews, reporting formats and use of adaptive clinical trials.
- Inspections v/s desktop reporting, prioritising additional Qualified Persons (QPs)
- Funding of pharmaceutical innovation during and after the COVID-19 pandemic
- What is the new frontier of regulatory submissions in post clinical trials?
- Reducing burdens to support better regulatory outcomes under the pandemic situation?
- The role of technology in Regulatory filings and deficiency

Moderator:

VISHWAS SOVANI

Founder Director
Pharmawisdom

Panellists:

OMPRAKASH S. SADHWANI

Former Joint Commissioner and Controlling Authority
FDA (Maharashtra state)

RAJENDRA SANGHAVI

Sr. Consulting Clinician & Medico-Marketing & TechnoRegulatory Consultant - Healthcare Industry & Chairman - Nutraceutical Committee, **Indian Drug Manufacturers' Association (IDMA)**

PRASANNA BANGALE

Vice President and Head, Global Regulatory Affairs
Alembic Pharmaceuticals

TAUSIF AHMED

Vice President & Head Biopharmaceutics & Bioanalytical
Global Clinical Management, **Dr. Reddy's Laboratories**

VAIBHAV CHOUDHARY

Joint Director, Medical and Clinical Affairs
Fresenius Kabi Oncology

GANESH KADHE

Senior Leadership Team Member, Scientific & Medical Affairs, **Abbott Nutrition**

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12:10 - Challenges in Global Biosimilar Development: A Regulatory Perspective

- Global Regulations: Where Do We Stand?
- Recent regulatory challenges over patents rights for biosimilars
- Biosimilars market regulation, what are the benefits and drawbacks?
- How can regulatory affairs boost the production of biosimilars?
- Should biosimilars have the same international non-proprietary name as the reference product?
- Future Regulatory Landscape

NAVANEETHA SELVAN

Associate Vice President - Global Regulatory Affairs
Wockhardt

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12:40 - Networking luncheon

PHARMACOVIGILANCE

13:40 - DISCUSSION WITH EXPERTS: New regulations in Pharmacovigilance and way forward

- What are expectations to be fulfilled by companies on the way to current regulations?
- Challenges in regulation of PV data management
- What are the regulatory aspects and risks analysis needed to revise before applying new technology in PV?
- Updates in guidelines for good PV practices
- Evaluating real-world evidence sources by regulators in PV

Moderator:

VIPIN SETHI
Global Pharmacovigilance Head - Medical Affairs
Cadila

Panellist:

SOFI JOSEPH
Regulatory Affairs & Pharmacovigilance Director
Serdia Pharmaceuticals

GEETA SHANBHAG
Sr. General Manager - Pharmacovigilance &
Medico-Regulatory Affairs, Ipca Laboratories

VARSHA KHATRY
Head Medical and Scientific Affairs, Quality and
Regulatory, Roche

SADANAND KULKARNI
Head-Medical, Regulatory, Vigilance, Quality
Fresenius Kabi

NEHA VALA
Head- Pharmacovigilance
Emcure Pharmaceuticals

IMPACT OF TECHNOLOGY

14:40 - The role of technology within regulatory compliance

- How is the Pharma regulatory environment influencing to adopt AI for?
- The role of AI within regulatory sciences and submissions
- AI's roles in quality standards and a regulatory framework
- An evidence-based strategy to maximize AI's benefits
- Regulatory impact analysis by using AI.

15:10- Afternoon Coffee/Tea & Discussion

15:30 - Recent trends in clinical development and regulatory strategies - New normal"

- Current approaches for clinical development strategy
- Regulation updates and evolving clinical trials approach
- Remote trials - finally the reality

VAIBHAV CHOUDHARY
Joint Director, Medical and Clinical Affairs
Fresenius Kabi Oncology

PATIENT SAFETY

16:00 - DISCUSSION WITH EXPERTS: Prioritizing patient safety regulations

- Encouraging the patient for direct reporting the adverse effect on drugs
- What are regulatory requirements in India for reporting of ADRs?
- New regulations on patient safety by WHO
- Comprehensive Guidelines for clinical and hospitals under new normal
- Open communication to ensure patient retention during clinical testing
- Ensuring the proper information delivered to patient regarding the trial or study.
- How could regulations and guidelines be implemented in patient safety?

Moderator:

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

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MAYUR PARMAR
Deputy Collector
Government of Gujarat

SAILAJA SAYANA
Senior Director & Head - Global Pharmacovigilance
Biocon

RISHI JAIN
Medical Director
AbbVie

ANUP CHOUDHURY
Associate Medical Director, Clinical Development
Novartis

ANJU AGARWAL
Director Global Patient Safety
Advanz Pharma

RAVI GAWARE
Head of Clinical Operations
Novo Nordisk

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16:50 - End of day one conference
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09:20 - Welcome Address & Virtual Conference Platform Instructions

DRUG DEVELOPMENT

09:30 - Drugs Development - Regulatory Challenges & Pro-active approach

VIPIN SETHI
Global Pharmacovigilance Head - Medical Affairs
Cadila

MEDICAL WRITING

10:00 - DISCUSSION WITH EXPERTS: Modern issues and maintaining quality in medical writing.

- Risks in lack of communication for outlining the aim, strategies and analysis in clinical writing
- Understanding the regulatory requirements and expectations in medical writing.
- Difficulties in the preparation of a good research article. What are the guidelines?
- Recent regulations in medical writing using AI
- Strategies for protocol development. Regulation is an obstacle?
- Changes in primary responsibilities for regulatory writers
- Overview of the document development process - from perspective of writers

Moderator:

RAJESH KHER
Director, Business Operations, Regulatory Medical Writing, **Janssen**

Panellist:

AMEY MANE
Director Medical Affairs
Dr. Reddy's Laboratories

VAIBHAV SALVI
Head - Medical Information, Asia
Sanofi

MANGALA KOTNIS
Head Regional Medical Affairs
Abbott

INDRANIL PURKAIT
General Manager and Head Medical Affairs
Ipsa Laboratories

MANJIRI WARANG
Medical Writing - Clinical Development
Sun Pharma

10:50 - Morning Coffee/Tea & Discussion

CLINICAL & REAL WORLD EVIDENCES

11:10 - DISCUSSION WITH EXPERTS: New regulatory challenges in clinical trials and ways for better usage of RWE

- Discussing the recent developments in GCP and clinical trial legislation.
- What can we expect for clinical development during post-pandemic? What are the hidden challenges in regulations?
- Stating the current status and future of RWE from the perspective of regulators
- Risk of combining RWE in the regulatory decision-making process.
- Outcomes and measures of implementation RWE in clinical activities.

Moderator:

Panellist:

RASHMI HEGDE
Executive Vice President Medical Affairs
GSK

PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines

SHIRAZ KANDAWALLA
Associate Director - Regulatory Affairs
Abbott

KAVITA LAMROR
Director, Real World Investigator, Digital Function
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MANISH MISTRY
Medical Director
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ASHWANI PANDITA

General Manager - Clinical Quality Management & Training, **Glenmark**

12:00 - Regulatory challenges in Usage of mobile apps in clinical trials current perspectives and future directions

KUMAR GAURAV

Director Medical Affairs
Dr. Reddy's Laboratories

12:20 - Networking luncheon

MEDICAL DEVICE

13:30 - DISCUSSION WITH EXPERTS: Evolving opportunities and challenges in medical devices regulations

- What is the regulatory environment for medical devices in India as per 'New Medical Devices Rules'?
- Better understanding of assessment and technical documentation for approval of medical devices?
- New regulatory framework for clinical investigation of medical device.
- Key themes for drug and medical device combination
- Business and regulatory strategies that can help medical devices succeed?
- Regulatory policies and technological innovation in medical devices - Where are we heading?

Moderator:

MILIND ANTANI

Leader, Pharma and Healthcare
Nishith Desai Associates

Panellist:

K BANGARURAJAN

Adviser
CDSCO (New Delhi)

PRAVEEN KUMAR L

Director - Regulatory Affairs
Cipla

YATEEN SHAH

Director - Regulatory Affairs & Quality
Johnson & Johnson

KRANTHI KIRAN PEBBILI

Director and Cluster Head - Medical Affairs
Dr. Reddy's Laboratories

SUMIT ANAND

Associate Director Clinical Operations
Abbott

RAJENDRA JANI

Senior Subject Expert & Advisor
Clinical Research Consultant

APARNA PRABHUNE

Asst General Manager Regulatory Affairs
Wockhardt

14:30 - COMMUNICATION: Diversity & Commonsense

- Types (media) & types (content)
- Key determinants of content
- Universal attributes of content: 5c attributes
- Universal attributes of presentations
- Execution
- Communication as applied to regulatory

AMIT BHARGAVA

Director
H.E.A.R.T of Medicine (Former VP, Lupin)

15:00- Afternoon Coffee/Tea & Discussion

15:20 - Regulations on interchangeability of biosimilar insulin: An Indian Perspective

SHAHU INGOLE

General Manager, Head Medical Affairs
Wockhardt

MANUFACTURING & SCM

15:50 - DISCUSSION WITH EXPERTS: Emerging challenges and opportunities in pharmaceutical manufacturing and supply chain.

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- Recent challenges and opportunities for Pharma manufacturing - Lessons learnt especially from the pandemic
- A better way to understand the CGMPs under post pandemic. What changes will take place in priorities?
- Guidelines to attain the total quality management (TQM)
- Regulatory challenges in active and inactive component
- Ways to improve the combination of quality, safety and effectiveness in manufacturing.
- What will be the major supply chain barriers that manufacturers will face in next few years?
- Ensuring the regulatory compliance in supply chain and steps to maintain transparency

Moderator:

VIPUL JAIN

Associate Director - SCM Integrated Business Planning
Cipla

Panellist:

SANJAY SHARMA

Vice President Technology Transfer
Lupin

VICKRAM SRIVASTAVA

Head of Planning - Global Supply Chain
Sun Pharma

SANJIV DONWALKAR

Head - Operational Excellence
Novartis

SUDIPTO BASU

Senior Manager - Demand Planning
Boehringer Ingelheim

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REGISTER ONLINE :

Link : <https://www.townscript.com/e/5th-annual-pharma-regulatory-summit-2022-312413>

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

REGISTRATION FORM

RESERVATION PRICING:

Early bird price - Valid till 24th January 2022

Cost per delegate

Fee: INR 7,000 + GST(18%)

Standard price - Valid From 25th January 2022

Cost per delegate

Fee: INR 9,000 + GST(18%)

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) ☐

Please keep my contact details confidential. Not to be shared to the other attendees - (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



CERTIFICATION



E-Certificate of attendance would be provided to attendees on request, upon completion of conference

Queries:

Should you have any questions on bookings, Please feel free to contact us.

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UK Office: Tel: +44-20 3509 3779

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.

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.

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