

17th Biosimilars Congregation 2022

#VIbsc

"Uniting industry leaders to analyse advanced commercial developments
& to identify successful management strategies of Biosimilars"

13th December 2022, Hotel Kohinoor Continental, Mumbai, India

AGENDA AT A GLANCE

Key Speakers
Conference Info
Day One
Floor Plan
Booking Details

Key Speakers Include



MUKESH KUMAR
Senior Vice President & Head, Clinical R&D
Cipla



ASHOK KUMAR
President - Centre for Research & Development
Ipca Laboratories



SATISH KOLTE
VP - Global Engineering & Project Head
Sun Pharma



SHALIGRAM RANE
Vice President & Site Head Quality
Lupin



RAHUL GUPTA
Vice President, Regulatory Affairs
USV



SANJEEV GUPTA
Vice President - Advanced Biotech Lab
Ipca Laboratories



SAMIR KULKARNI
Director, National Center for Nano-science and
Nanotechnology



KETAKI SABNIS-PRASAD
Assistant Director & Head Development
Quality Assurance Biotech, Lupin



SHAHU INGOLLE
General Manager, Head Medical Affairs
Wockhardt



MOHIT AGARWAL
Head of Emerging Markets - SFE
Sun Pharma



VENKAT NATARAJAN
Heading Access Initiatives
Pfizer



HARSHAD KOTHAWADE
Head-Regulatory Management & Trade
Compliance, Merck



AKSHAYA ODAK
Head - Regulatory (Biotech)
Lupin



SHASHIN BODAWALA
Former Director - Business Excellence, Go To
Market & International Business, Boehringer
Ingelheim



SANTOSH JADHAV
Deputy General Manager - Quality Control
Bharat Serums and Vaccines



APARNA PRABHUNE
Asst General Manager Regulatory Affairs
Wockhardt



VISHWAS SOVANI
Founder Director
Pharmawisdom



SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions



ROSHAN PAWAR
Associate General Manager
Alkem Laboratories



GAURAV AGARWAL
New Product Introduction Project Manager
Abbott



KAVYA KADAM
Consultant Global Clinical Trials

PLUS MORE COMING SOON...

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KEY THEMES DISCUSSED:

- Analyzing the current situation and future trends in development of biosimilars
- Identifying the best market practices for Biosimilars
- Global commercialization strategies: How to strategically build a global biosimilars portfolio?
- Future of Interchangeability – What has to be done?
- Reference product and the biosimilars – How to maintain the relationship?
- What are the current market trends affecting the biosimilar? Especially under post-pandemic
- New product and existing product strategies to maintaining sustainability in biosimilars
- Fresh trends in background, objective and approach towards patent rights
- Challenging patent rights on reference product
- Analytics - How will it help to make things better in product development?
- Ensuring the balance between product development and patient safety
- Effect of potential strategies on development of interchangeability and generics
- Scalable, faster, efficient biosimilars processes – Better ways
- Interchangeability and switching biosimilar: Regulatory's view
- Clinical-phase-appropriate regulatory compliance in the development of biosimilars
- Be part of a major networking opportunity

WHO SHOULD ATTEND: -

CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, and Senior Scientists from the following roles:

- Biopharmaceuticals/ Biotherapeutics
- Follow on Biologics/Follow on Proteins
- Biologics/Biotechnology/ Bio generics
- Legal Affairs
- Intellectual Property
- Health Economics
- Pricing and Reimbursement
- Clinical Immunology
- Principal Scientist
- Chief Scientific Officer
- Process Control and Analytical Technologies
- Analytical Characterisation
- Regulatory Compliance
- Pharmacovigilance
- Drug Safety & Risk Management
- Quality Affairs/ Quality Control
- New Product Development
- Process Science
- Portfolio Management
- Research & Development
- Business Development
- Business Operations
- Scientific Affairs
- Commercial Affairs

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DAY ONE - 13th December 2022

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

09:20 – Chairperson opening remarks

CHALLENGES & OPPORTUNITIES

09:30 – Situation of Biosimilar's Market – Pros and Cons

- Identifying the best market practices for Biosimilars
- Spotlight on international markets – how to handle the foreign market's regulations
- New and recent trends in emerging the markets of Biosimilars
- Global commercialization strategies: How to strategically build a global biosimilars portfolio?

10:00 – DISCUSSION WITH EXPERTS: Biosimilars 2022
Analyzing the potential challenges

- Biosimilars manufacturing – Expectations Vs reality
- Future of Interchangeability – What has to be done?
- Real world challenges in implementation of Biosimilars
- Clinical trials and Pharmacovigilance for biosimilars – What are recent developments?
- Reference product and the biosimilars – How to maintain the relationship?
- Biosimilars in rare diseases: An opportunity

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

ASHOK KUMAR
President – Centre for Research & Development
Ipca Laboratories

SHALIGRAM RANE
Vice President & Site Head Quality
Lupin

SHAHU INGOLE
General Manager, Head Medical Affairs
Wockhardt

ROSHAN PAWAR
Associate General Manager
Alkem Laboratories

KAVYA KADAM
Consultant Global Clinical Trials

10:50 – Morning Coffee/Tea & Discussion

MARKET ACCESS & IMPLEMENTATION

11:10 – DISCUSSION WITH EXPERTS: Unique challenges
to market access for Biosimilars

- What are the current market trends affecting the biosimilar?
- Addressing the challenges of market implementation in biosimilar especially under post-pandemic
- Entry strategies, countermeasures to economic impact & marketing channels
- Key factors that impacting market and economic growth
- New product and existing product strategies to maintaining sustainability in biosimilars

Moderator:

Panellists:

SHASHIN BODAWALA
Former Director – Business Excellence, Go To Market &
International Business, Boehringer Ingelheim

MOHIT AGARWAL
Head of Emerging Markets – SFE
Sun Pharma

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12:00 – Patent rights – Challenges and benefits

- New trends in background, objective and approach towards patent rights
- Recent FDA rules that affecting the patent rights
- Best plan and strategy for patent right on generic drugs
- Challenges in patent rights on reference product

12:30 – Networking luncheon

PRODUCT DEVELOPMENT

13:40 – DISCUSSION WITH EXPERTS: Future direction for product development in Biosimilars

- Analytics - How will it help to make things better?
- Upstream processing & Downstream processing – Risk and benefits
- Risk of adverse effects related to new drug development. How to overcome that?
- How to keep ensuring the balance between product development and patient safety?
- How to speed up the process of development and reduce costs of production?
- Product compatibility and regulatory aspects

Moderator:

Panellists:

MUKESH KUMAR
Senior Vice President & Head, Clinical R&D
Cipla

SATISH KOLTE
VP – Global Engineering & Project Head
Sun Pharma

SANJEEV GUPTA
Vice President - Advanced Biotech Lab
Ipca Laboratories

SAMIR KULKARNI
Director
National Center for Nano-science and Nanotechnology

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

14:40 – Device and its component testing for drug device combination products

SANTOSH JADHAV
Deputy General Manager - Quality Control
Bharat Serums and Vaccines

15:10– Afternoon Tea/Coffee

15:30 – Future of Biopharma industry

KETAKI SABNIS-PRASAD
Assistant Director & Head Development Quality Assurance Biotech, Lupin

REGULATORY

16:00 - DISCUSSION WITH EXPERTS: Overview of regulatory guidelines for Biosimilars

- What are the recent developments in regulatory that impact the biosimilar industry?
- Regulatory requirements for approval of biosimilars
- Interchangeability and switching biosimilar: Regulatory's view
- Clinical-phase-appropriate regulatory compliance in the development of biosimilars
- FDA and EU regulatory – What can be learnt from that side towards our market?

Moderator:

Panellists:

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

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Head-Regulatory Management & Trade Compliance
Merck

AKSHAYA ODAK
Head - Regulatory (Biotech)
Lupin

APARNA PRABHUNE
Asst General Manager Regulatory Affairs
Wockhardt

.....
16:50 – Chairperson closing remarks and end of the
conference
.....

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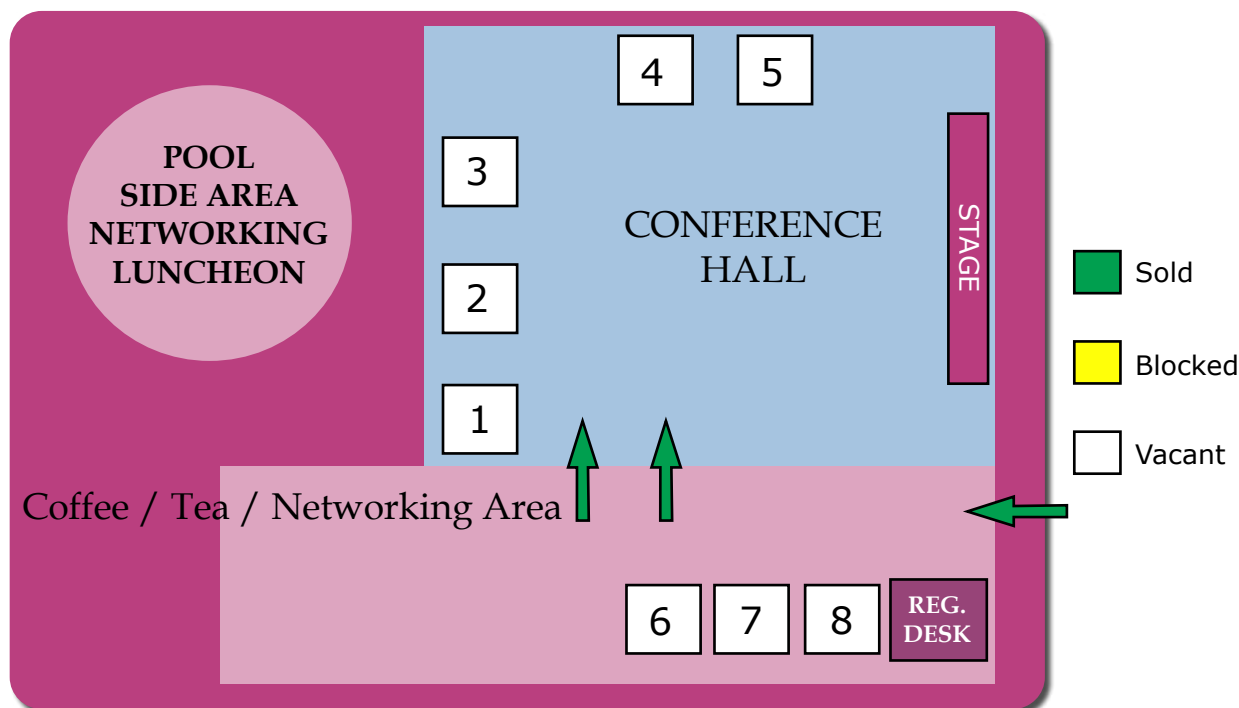
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FLOOR PLAN - Book your stalls now before they run out !!!



1	5
2	6
3	7
4	8

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

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REGISTER ONLINE :

Link : <https://www.townscript.com/e/17th-biosimilars-congregation-2022-131221>

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

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Price (Valid Till 31st October 2022)

Cost per delegate - Fee: INR 10,000 + GST(18%)

Standard Price (Valid From 01st November 2022)

Cost per delegate - Fee: INR 15,000 + GST(18%)

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.

Email: info@virtueinsight.com
Web: <http://www.virtueinsight.com>
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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 (Subject to availability) - Please email to
bookings@virtueinsight.com

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.

Covid Situation - In the case where the government of Maharashtra decide
to go into a lockdown or restrictions on social and business gatherings during
the dates of the conference, the event will be postponed to a new date. Reg-
istered clients can choose to join the conference on the new date or decide to
take a credit note for their payment so that they can decide to participate for
any of our future events within the timeframe of next one year from the time
we start hosting live events as soon as the lockdown restrictions are lifted by
the government.

VENUE

Kohinoor Continental Hotel

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

CLICK
HERE
for more details

MAP & DIRECTIONS

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