16th Biosimilars Congregation 2021

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

09th December 2021, Virtual Conference (Time Zone – IST)

#VIbsc

AGENDA AT A GLANCE

Key Speakers Include

ARANI CHATTERJEE
Senior Vice President, Clinical Research
Aurobindo Pharma

PHILIP SCHNEIDER
Chair, International Advisory Board
Alliance for Safe Biologic Medicines(USA)

MICHEL MIKHAIL
International Expert in Regulatory Affairs, Global Expert in Biosimilars (Germany)

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

MARTA BALDRIGHI
Policy and Science Officer
Medicines for Europe (Belgium)

SHALIGRAM RANE
Vice President of Quality
Lupin

NARENDRA MAHARAJ
Vice President and Head, Clinical Development and Biologics Dr. Reddy's Laboratories

PRAVIN KULKARNI
Vice President – Quality (Biotech)
Wockhardt

PRAVEEN KUMAR L
Director - Regulatory Affairs
Cipla

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

PIRTHI PAL SINGH
Vice President
Tirupati Group

PAWAN SINGH
Senior Medical Director
Biocon

KUMAR GAURAV
Director Medical Affairs
Dr. Reddy's Laboratories

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

ARUN BHATT
Consultant – Clinical Research & Development

NITISH CHAKRAVARTY
Vice President - Secondary Manufacturing
Biological E

KANTHIKIRAN VARANASI
Vice President and Head - Clinical Research & Operations, Galenicum

ADITYA SHARMA
Head - BioProcessing Business
Merck Life Science

UDIT SAKHUJA
Head of Marketing
Dr. Reddy's Laboratories

SONAL SHAH
Head Marketing – Biosimilars
Cadila

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MANISH MAHAJAN
DGM- Medical Affairs
Cadila Healthcare (BU- Biologics)

RAHUL CHAUHAN
Head - Regulatory Affairs
Takeda

NAGENDRA RAMANJINAPPA
Head Medical Affairs
Viatris

SWEETY MATHEW
Global Regulatory Affairs
Biocon

ALOK SHARMA
Head & GM, Quality Control
Lupin

TUSHAR NAIK
Consultant & Advisor, GLG(USA) (Former Senior GM, Zydus Group)

RAVI SHANKARA
Sr. GM (R & D) & Functional Head -Analytical Development - Biologics and Peptides
Sun Pharma

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

MAHENDRA SHIRADKAR
Lead: FDS Project and Portfolio Management
Viatris

PRAVIN A. NAIR
Head, Drug Product Development (R&D)
Intas Pharmaceuticals (Biopharma Division)

KAVYA KADAM
Consultant, Global Clinical Trials

HARSHAD KOTHAWADE
Head-Regulatory Management & Trade Compliance, Merck

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AGENDA AT A GLANCE

CONFERENCE INTRODUCTION

The global biosimilars market size is expected to grow from USD 35.7 billion by 2025 from USD 11.8 billion in 2020, at a CAGR of 24.7%. However, with complexities in manufacturing and resistance from biologic manufacturers, such factors keep adding to the hindrance in their development.

2030, India will become the sixth-largest market for pharmaceuticals, and it has firmly established itself in the global biopharmaceutical market. Many of the Indian pharmaceutical companies are preparing to step into the global biosimilars market. As per the report of 2017, biosimilars represent a 30% compound annual growth rate. They are worth $2.2bn out of the $32bn total Indian pharma market and are estimated to reach $40bn by the year 2030.

Virtue Insight is delighted to invite you to attend the 16th Biosimilars Congregation 2021 conference, to be held on 09th December 2021(Virtual Conference). 16th Biosimilars Congregation 2021 brings together scientists, researchers and CROs from around the world.

At 16th Biosimilars Congregation 2021 meet your target audiences from around the world focused on learning about biologics and biosimilars. This conference would be your single best opportunity to reach the largest assemblage of participants from the biologics and biosimilars community

Why to attend???

Join your peers around the world focused on learning about Biologics and Biosimilars related advances, which is your single best opportunity to reach the largest assemblage of participants from the Biosimilars community, conduct demonstrations, distribute information, meet with current and potential professionals, make a splash with new research works, and receive name recognition at this 1-day event. Well-renowned speakers, the most recent research, advances, and the newest updates in Biologics and Biosimilars are hallmarks of this conference.

We look forward to see you virtually.

KEY THEMES DISCUSSED

- Recent trends and new normal in Biosimilars - How to excel with this?
- Development challenges on the biosimilars products for companies? What are the remedies?
- Pharmacovigilance and risk management of biosimilars.
- Successful business models and dealing with every ambiguity
- mAbs - Could be a game changer in India
- Impact of the pandemic - affecting the biosimilar markets
- Ways for smart handling of market access, sustainable pricing and reimbursement of biosimilars in the market.
- Challenges and changes interchangeability
- How does strategic planning really help to grow market opportunities?
- Market barriers for biosimilar approval in India market.
- Future opportunities for product development
- Risk of adverse effects related to new drug development. How to overcome that?
- Newer versions of generic drugs truly increase the value of the market?
- How to speed up the process of development and reduce costs of production?
- Regulators view on interchangeability and switching biosimilars.
- How to minimise the rejection of biosimilar applications while evaluating regulatory bodies?
- Next 5 years in the field of biosimilars regulations

WHO SHOULD ATTEND AND WHO YOU'LL MEET

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 Affair

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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09th December 2021, Virtual Conference (Time Zone – IST)

DAY ONE - 09th DECEMBER 2021

09:20 - Welcome Address & Virtual Conference Platform Instructions

REGULATIONS FROM USFDA & EMA

09:30 – Overview of the regulatory considerations for Biosimilar product development

SWEETY MATHEW
Global Regulatory Affairs
Biocon

CHALLENGES & OPPORTUNITIES

10:00 – DISCUSSION WITH EXPERTS: Recent trends and new normal in Biosimilars

- Most significant challenges in biosimilars for manufactures - vision for future and implementation of technology in production
- What is the new normal in Biosimilar? How to excel with this?
- Development challenges on the biosimilars products for companies? What are the remedies?
- New product targets for biosimilar development
- Pharmacovigilance and risk management of biosimilars.
- How is global biosimilar the player of fast-changing commercialised world?
- Key success factors in biosimilar policy
- Real World Evidence studies for Biosimilars
- Interchangeability and switch ability
- Regulatory audit approval – challenges and its management

Moderator:

NARENDRA MAHARAJ
Vice President and Head, Clinical Development and Biologics
Dr. Reddy's Laboratories

Panellists:

SHALIGRAM RANE
Vice President of Quality
Lupin

PAWAN SINGH
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Consultant – Clinical Research & Development

NAGENDRA RAMANJINAPPA
Head Medical Affairs
Viatris

KAVYA KADAM
Consultant, Global Clinical Trials

11:00 – Morning Coffee/Tea & Discussion

REGULATORY

11:20 - DISCUSSION WITH EXPERTS: Analyzing the recent developments of regulatory in biosimilars.

- What are the recent developments in regulatory? How it is impacting the Pharma industry?
- Regulatory changes necessary to maximize biosimilars potential
- Regulators view on interchangeability and switching biosimilars.
- Legal hurdles to bring a biosimilar product to market
- What types of additional risk minimisation measures may be necessary?
- What are the developments we can expect in the next 5 years in the field of biosimilars regulations?

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

PRAVEEN KUMAR L
Director - Regulatory Affairs
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DAY ONE - 09th DECEMBER 2021

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DGM- Medical Affairs
Cadila Healthcare (BU- Biologics)

RAHUL CHAUHAN
Head - Regulatory Affairs
Takeda

12:20 – GMP trends for Biosimilars & Way forward

PRAVIN KULKARNI
Vice President – Quality (Biotech)
Wockhardt

12:50 - Networking luncheon

PRODUCT DEVELOPMENT

13:40 – DISCUSSION WITH EXPERTS: Discussing the hidden hurdles in product development in biosimilars.

- Next steps to evaluate the future opportunities for product development
- What are the potential strategic impacts on development? How does it work especially under pandemic times?
- Risk of adverse effects related to new drug development. How to overcome that?
- Newer versions of generic drugs truly increase the value of the market
- How to keep ensuring the balance between product development and patient safety? What are alternative ways that makes easier?
- Major and recent hurdles for healthcare providers in switching from reference products to biosimilars
- How to speed up the process of development and reduce costs of production?

Moderator:

PIRTHI PAL SINGH
Vice President
Tirupati Group

Panellists:

ARANI CHATTERJEE
Senior Vice President, Clinical Research
Aurobindo Pharma

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Director
National Center for Nano-science and Nanotechnology

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PRAVIN A. NAIR
Head, Drug Product Development (R&D)
Intas Pharmaceuticals (Biopharma Division)

INTERCHANGEABILITY

14:40 – Interchangeability of Biosimilar products

- What is interchangeability?
- US- FDA Approval of First Interchangeable Biosimilar: Mylan's Insulin Semglee (insulin glargine-yfgn)
- Automatic substitution of this interchangeable Insulin will shift the Diabetes Market towards Biosimilars
- Learning from the US interchangeability for the Indian Market

MICHEL MIKHAIL
International Expert in Regulatory Affairs, Global Expert in Biosimilars (Germany)

15:10 – Afternoon Coffee/Tea

15:30 – The WHO SBP guideline revision: a chance to build on experience to achieve a more efficient regulatory landscape

- The WHO is currently revising its Similar Biotherapeutics Products (i.e. biosimilar medicines) guideline.
- This important revision happens as discussions are intensifying worldwide on how to achieve regulatory streamlining.
- Among the necessary steps to reach regulatory streamlining, embracing regulatory science advances, increased international convergence among regulators, and a concerted global roadmap for implementation of clinical trial tailoring will be key.

DAY ONE - 09th DECEMBER 2021

- The input of biosimilar medicines manufacturers, provided through 2 rounds of public consultation on the new guideline draft, will be essential in ensuring fit-for-purpose guidance.

MARTA BALDRIGHI
Policy and Science Officer
Medicines for Europe (Belgium)

MARKET ACCESS & IMPLEMENTATION

16:00 – DISCUSSION WITH EXPERTS: Market Access - Key challenges and points for successful tomorrow market.

- What are the current trends affecting the biosimilar markets?
- Ways for smart handling of market access, sustainable pricing and reimbursement of biosimilars in the market.
- How to discover, estimate, and plan for entry opportunities?
- Addressing the challenges of market implementation in biosimilar.
- What are the ethical developments needed to make a better biosimilars market?
- Identifying the particular market barriers for biosimilar approval in India market.
- Sharing the knowledge towards policy implementation of biosimilar as driver in the market.

Moderator:

PHILIP SCHNEIDER
Chair, International Advisory Board
Alliance for Safe Biologic Medicines(USA)

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Head - BioProcessing Business
Merck Life Science

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Cadila

MAHENDRA SHIRADKAR
Lead: FDS Project and Portfolio Management
Viatris

TUSHAR NAIK
Consultant & Advisor, GLG(USA) **(Former Senior GM,** Zydus Group**)**

17:00 – End of the Conference

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REGISTER ONLINE :

Link : https://www.townscript.com/e/16th-biosimilars-congregation-2021-313032

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

REGISTRATION FORM

RESERVATION PRICING:

STANDARD PRICE

Cost 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 .....

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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.

Email: info@virtueinsight.com
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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.