

14th Biosimilars Congregation 2019

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

12th December 2019,
Kohinoor Continental Hotel,
Mumbai, India



AGENDA AT A GLANCE

Key Speakers Include



ASHOK KUMAR
President Centre for Research & Development
Ipca Laboratories



MAYUR PARMAR
Deputy Collector
Government Of Gujarat



RISHI JAIN
Vice President, Medical, Clinical & Regulatory
Affairs, India Business & ROW, **Wockhardt**



MAYRA GUZMAN-KASLOW
President & CEO, GK Pharmaceutical Contract
Manufacturing Operations (Puerto Rico, USA)



ARUN BHATT
Consultant - Clinical Research & Development



OMPRAKASH S. SADHWANI
Former Joint Commissioner and controlling
Authority, Food and Drug Administration
(Maharashtra state)



SAMIR KULKARNI
Director Innovation, Incubation and Linkages
(Director, National Center for Nanoscience and
Nanotechnology), University of Mumbai



S.R. SALUNKHE
Former Assistant commissioner
FDA Maharashtra



RAHUL GUPTA
Vice President, Regulatory Affairs
USV



DEEPA ARORA
Director
Clinixel Life Sciences



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



ALAP GANDHI
Head- Medical Affairs
GSK



SRIVANI MUKKAMALA
Independent Consultant



GAURAV AGARWAL
Biosimilars Program Manager
Wockhardt



SANDEEP JAGTAP
Assistant General Manager (Global Clinical
Development), **Mylan Pharmaceutical**



MUJTABA HUSSAIN NAQVI SYED
Team lead, Ideation, Medical Affairs
Dr. Reddy's Laboratories



CHIRAG BHATT
Head-Quality
MIV Therapeutics (India)



UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics



VINAYAKA SHAHAVI
Associate General Manager
Alkem Laboratories



HARSHAD RASANE
Associate Centralized Monitoring Lead
IQVIA



PRANJAL BORDOLOI
Vice President - Clinical Medical Affairs & PV
Veeda Clinical Research



VISHWAS SOVANI
Founder Director
Pharmawisdom



SAKHARAM GARALE
Head South-East Asia Operations ACMA &
Managing Partner
RENOVARE Healthcare Solutions

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#Vlbosc

"Very well organised & very interesting topics selected. Time management & allowing to ask questions were very sufficient as well."

Head of Clinical Operations - Emerging Markets, Boehringer Ingelheim

AGENDA AT A GLANCE



KAVYA KADAM
Consultant Global Clinical Trials



RAJASHREE GADGIL JOSHI
Founder & CEO
ENERGYA - RSG Nutrition & Healthcare



THOMAS PHILIP
Senior Manager Digital Strategy and Analytics
Cipla



RISHAB KAPOOR
Research Scientist
APAC Biotech



HEMANT ZAVERI
General Manager - Head Medical Affairs
Otsuka Pharmaceuticals



PRASHANT BODHE
Director
CLINISEARCH

WHO ATTENDS?

30+
Speakers

70%
Decision
Makers

3+
Hours of
Networking

1
Day

1
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Opportunity

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EXHIBITOR



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"Great opportunity for networking and to learn different industry perspectives on PV systems, challenges & regulations."

Regulatory Inspection Lead, Safety & International
Global Quality, Takeda

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

According to a recent report by Morgan Stanley, as many as nine drugs in the biologics category have either gone off patent or will do so by 2025. Their total revenue was \$62 billion (around INR 4.3 lakh crore) in 2018. This creates a major opportunity for their respective biosimilars. The research firm estimates that revenue of these biosimilars will grow by 24 per cent annually for seven years to \$13.3 billion in 2025 (around INR 93,000 crore) in the US and Europe. That offers a big opportunity. the global market for biosimilars will be \$240 billion and the Indian market will be over \$35 billion by 2030

The 14th Biosimilars Congregation 2019 will be your opportunity with leading industry experts to discuss from development, manufacturing to commercialization - The current landscape, legal, regulatory, funding, challenges, market access strategy, business models and how to get to market

Virtue Insight is delighted to invite you to attend the 14th Biosimilars Congregation 2019 conference, to be held on 12th December 2019 in Mumbai, India. 14th Biosimilars Congregation 2019 brings together scientists, researchers and CROs from around the world.

At 14th Biosimilars Congregation 2019 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 personally at our esteemed event.

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Biosimilar companies ' market assessment - Where are we to ahead?
- Present state and future scenario of the biosimilar market.
- Why does India need biotechnology to guarantee the safety of food, feed and nutrition?
- What are Indian institutes and scientists ' innovative biotechnological methods?
- Current landscape and policy updates for global biosimilars
- Discussing pricing approach and value management as a growing need
- Current challenges in developing biosimilars
- Scientific and strategic approaches taken for successfully developing of follow-on-biologics
- How and when should investors be involved in biotech funding?
- Product processing and production, permits and licensing and other direct costs
- Biosimilars & Biobetters development
- Product development, marketing authorisation and post-registration surveillance differences between generics and biosimilars
- Discussing about the growth statistics of biopharmaceutical industry in India
- Challenges faced in the development and production of biosimilars
- Regulatory authorities guidelines for the advancement and approval of biosimilars
- Strategies for better regulatory expertise and cross-nation support for advance regulatory policy innovation
- 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

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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"Insightful sessions, well structured presentations and speakers sharing highly valuable knowledge and experience. Learned a lot even through the networking breaks."

PhV Manager, Teva Pharmaceutical

AGENDA AT A GLANCE

DAY ONE - 12th December 2019

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

MARKET OVERVIEW & ANALYSIS

09:30 / Biosimilars : Concepts and Controversies

RISHI JAIN

Vice President, Medical, Clinical & Regulatory Affairs, India
Business & ROW, **Wockhardt**

CHALLENGES & OPPORTUNITIES

10:00 / DISCUSSION WITH EXPERTS: Current landscape and policy updates for global biosimilars

- Biosimilar companies' market assessment – Where are we to ahead?
- Establishing a prosperous biosimilar market for other nations around the globe in terms of accessibility, investment, competition, regulatory approach, and other facets.
- Establishing similarity with the original medicine while finding the original molecular clone
- Discussing on the development of biosimilar production capabilities along with overall high cost of development
- Addressing rigorous and long regulatory paths in different nations
- Discussing pricing approach and value management as a growing need
- In the coming months, what topics will shape the sector, and how can players distinguish themselves?

Moderator:

S.R.SALUNKHE

Former Assistant commissioner
FDA Maharashtra

Panellists:

MAYUR PARMAR

Deputy Collector
Government Of Gujarat

OMPRAKASH S. SADHWANI

Former Joint Commissioner and controlling Authority
Food and Drug Administration (Maharashtra state)

HEMANT ZAVERI

General Manager Head Medical Affairs
Otsuka Pharmaceuticals

MUJTABA HUSSAIN NAQVI SYED

Team lead, Ideation, Medical Affairs
Dr. Reddy's Laboratories

KAVYA KADAM

Consultant Global Clinical Trials

10:40 – Morning Coffee/Tea & Discussion

11:00 / DISCUSSION WITH EXPERTS: Current challenges in developing biosimilars

- Scientific and strategic approaches taken for successfully developing of follow-on-biologics
- Overcoming the difficulties of late clinical steps, drug safety factors and requirements for labelling
- Focusing on multiple aspects of biosimilars product development to successfully deliver safe, potential and efficacious biologic products to the market
- Does the industry have sufficient tools and technologies to partner and deliver services to the public sector?
- What is the current stage of development and hindrances in fast-tracking translational research?
- Opportunities – Models of business and investment
- Portfolios of biosimilar products and business strategies

Moderator:

PRASHANT BODHE

Director
CliniSearch

Panellists:

ARUN BHATT

Consultant – Clinical Research & Development

SRIVANI MUKKAMALA

Independent Consultant

GAURAV AGARWAL

Biosimilars Program Manager
Wockhardt

HARSHAD RASANE

Associate Centralized Monitoring Lead
IQVIA

VINAYAKA SHAHAVI

Associate General Manager
Alkem Laboratories

11:50 / "Clinical strategies for global biosimilar development"

SANDEEP JAGTAP

Assistant General Manager (Global Clinical Development)
Mylan Pharmaceutical

12:20 / Gateway of the Biosimilars to Puerto Rico

MAYRA GUZMAN-KASLOW

President & CEO, GK Pharmaceutical Contract Manufacturing, Operations (Puerto Rico, USA)

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#VIbsc

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"The conference was very well organised and speakers were clear and concise. I enjoyed the panel discussions as it was good to hear different opinions which are based on experiences etc."

Manager - Pharmacovigilance, Kinapse (Syneos Health)

AGENDA AT A GLANCE

DAY ONE - 12th December 2019

12:50 - Networking luncheon

Afternoon Chair Person

13:50 Biosimilars Perspective - Current Regulatory Scenario for Medical Devices

- Current Market of Medical Devices
- Why Separate regulation Required for Medical Devices?
- Current Medical Devices Regulation of World wide.
- Current Medical Devices Regulation in India.
- Expectation from Govt related to Regulation.

CHIRAG BHATT
Head-Quality
MIV Therapeutics (India)

14:20 DISCUSSION WITH EXPERTS: Discussing about the growth statistics of biopharmaceutical industry in India

- Challenges faced in the development and production of biosimilars
- Investigate whether pricing points are fulfilled or if other determinants need to be articulated
- Planning of a biosimilar development project - what to consider from the very beginning?
- Evaluate the financial development of biosimilars in the global healthcare marketplace
- Mastering the present market movement to learn and cause biosimilar commercial success
- Moving forward: strategies to optimise growth from a quality standpoint
- Addressing the challenging perspectives where the development of biosimilars and generics should be addressed

Moderator:

PRANJAL BORDOLOI
Vice President - Clinical, Medical Affairs & Pharmacovigilance
Veeda Clinical Research

Panellists:

SAMIR KULKARNI
Director Innovation, Incubation and Linkages (Director, National Center for Nanoscience and Nanotechnology), University of Mumbai

RAJASHREE GADGIL JOSHI
Founder & CEO
ENERGYA - RSG Nutrition & Healthcare

THOMAS PHILIP
Senior Manager- Digital Strategy and Analytics
Cipla

RISHAB KAPOOR
Research Scientist
APAC Biotech

SAKHARAM GARALE

Head South-East Asia Operations ACMA & Managing Partner
RENOVARE Healthcare Solutions

15:00 - Afternoon Tea/Coffee

15:20 Biosimilars : Hype, Hope and Beyond

- Why Biosimilars?
- Few must knows about Biosimilars
- Challenges
- The way forward
- Conclusion

ASHOK KUMAR
President - Centre for Research & Development
Ipca Laboratories

REGULATORY

16:10 DISCUSSION WITH EXPERTS: Biosimilars in India: Regulatory Scenario, Best foot forward

- Biosimilars regulatory landscape: Indian perspective
- Strategies for better regulatory expertise and cross-nation support for advance regulatory policy innovation
- Leveraging regulatory landscape to launch biosimilars products in India
- How the agency intends to move certain presently authorized biological products to be certified as biological products
- Guidance and proposed rule to advance biosimilars policy framework
- Guidelines for regulating the production process and the quality, security and effectiveness of comparable biologics
- Aspect of Clinical Development and Safety surveillance aspects of Biosimilar
- Key challenges in implementation of regulations

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

RAHUL GUPTA
Vice President, Regulatory Affairs
USV

DEEPA ARORA
Director
CLINEXEL Life Sciences

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

ALAP GANDHI
Head, Medical Affairs
GSK

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#VIbsc

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"Well discussed topics with a distinguished and prolific panel of experts in their respective fields in Biosimilars"

Senior Business Analyst, Jakob & Partners

AGENDA AT A GLANCE

DAY ONE - 12th December 2019

UJWALA V. SALVI
Founder & Chief Executive Officer
Nucleon Therapeutics

CHIRAG BHATT
Head-Quality
MIV Therapeutics (India)

16:50 - Chairperson's closing remarks and end of conference

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#Vlpsc

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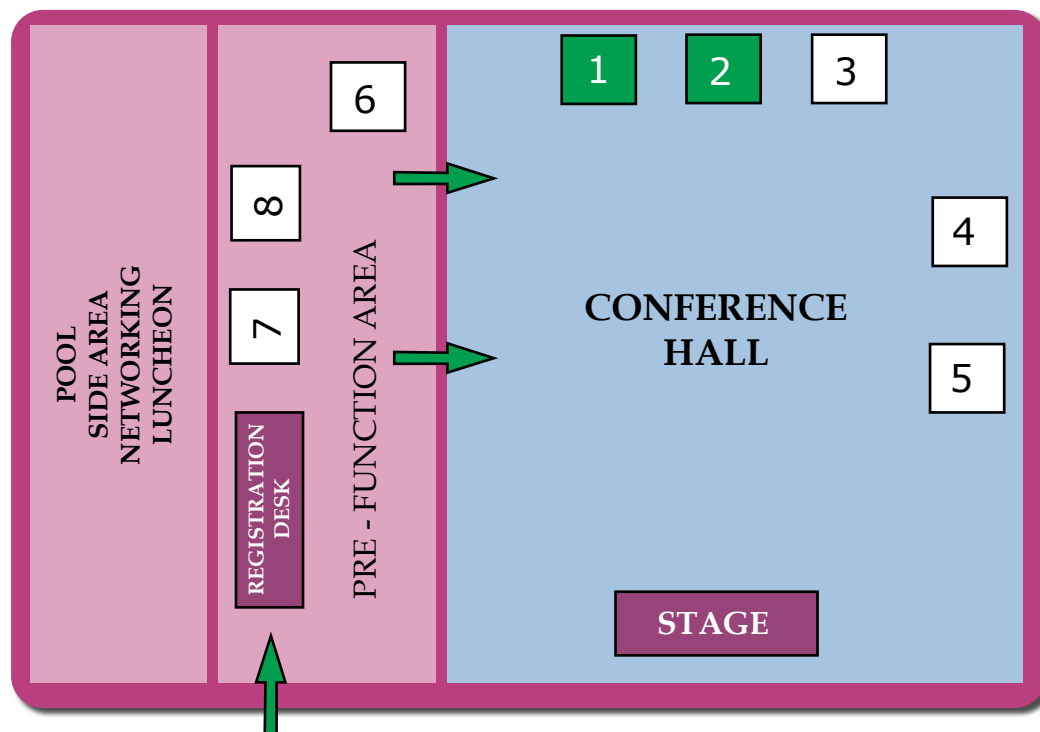
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"A great platform to understand the current practices & situation all across the industry, as well as individual approach of each company toward the goal of patient safety."

Senior Executive, Lupin

AGENDA AT A GLANCE

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



4

7



5

8

3

6

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

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"Really top-tier collaboration and experts present at this event. From amazing hosts and chairman to a wonderful venue, this is the PV event that will make an impact on the industry for how we change how we do work."

Head of Clinical Quality, Karyopharm Therapeutics

REGISTER ONLINE :

Link : <https://www.bookmytrainings.com/catalogue/event/72366-14th-biosimilars-congregation-2019>

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

REGISTRATION FORM

RESERVATION PRICING:

Standard Rate

1 day conference per delegate - Fee: INR 10,000 + GST(18%)

For Bulk Booking of More Than 5 Delegates

Please email us at bookings@virtueinsight.com

Registration Form Details:

ForenameSurname

Job Title

Company

GST No (If Applicable)

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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:

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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 42108101

General Information Venue:

Kohinoor Continental Hotel
Andheri Kurla Road
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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 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

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Phone: 91 22 66919000 /
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MAP & DIRECTIONS

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