



# **11<sup>th</sup> Biosimilars Congregation 2017**

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

**06<sup>th</sup> December 2017, Kohinoor Continental Hotel, Mumbai, India**

## **KEY THEMES DISCUSSED: -**

- Discussing country-specific & strategies on market access of biosimilars
- Role of patient groups and importance of patient-centric approaches – solving and shaping your access strategy
- Exploring ways to break into India's private market
- What are the current demands on vaccines in India?
- What is the future consideration for biosimilar and how is the biosimilar market formulating globally?
- What are the terms of regulations and IP stands before biosimilars?
- Biosimilar and Biobetters development
- Manufacturing biologics: How to prevent human errors using automation
- Biosimilars in India: What's next? Consideration for long term market sustainability and market access strategies, opportunities and commercial challenges
- Technology transfer strategies for market access
- Licensing, partnerships and strategic alliance management
- What should you be looking for in your partners and how can you make your business more attractive to them?
- Safety & Risk Management System for Biosimilars
- Regulatory framework for risk management
- Biosimilar regulations and development updates
- Strategies for improving regulatory expertise and cross-nation support for promoting regulatory policy innovation
- Be part of a major networking opportunity

## **CONFERENCE INTRODUCTION: -**

Virtue insight is proud to present its **11<sup>th</sup> Biosimilars Congregation on 6th December 2017 in Mumbai – India**. Discussing strategies for biosimilar product development Indian Pharmaceutical companies have started to look at biosimilars as a lucrative sector owing to the recent regulatory approvals and revenue generating opportunities.

Though biosimilars are less costly versions of the biologics, their development is much more complex, this makes their regulatory approval more difficult when compared to generic drugs. However, with many leading biologics losing their patent protection by 2020; the market entry and opportunity for biosimilars is set to expand

Asia Pacific alone develops more biosimilar products than anywhere else in the world and regulatory bodies are putting more resources to handle biosimilars applications and more biopharma companies to develop biosimilars products. This event will discuss commercial strategies, insights on how regulatory & approval process work in region, opportunities for market expansion and highlights on R&D. Join us to explore the current global climate for biosimilars,

**For more info, please contact Nisith Ranjan Binod, Production Manager, Virtue Insight:  
Tel: + 91 44 64998743, Email: [nisith@virtueinsight.co.in](mailto:nisith@virtueinsight.co.in)**



evaluate competition and benchmark with industry peers on how to navigate the changing regulations and landscape of the biosimilars market and effectively bring these programs to market.

#### 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/ Biogenics
- 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

#### 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 drinks 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. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margin

**06<sup>th</sup> December 2017**

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

**09:30 – Chairperson opening remarks**

## **MARKET OVERVIEW & ANALYSIS**

**09:40 – Discussing country-specific & strategies on market access of Biosimilars**

- The barriers to market access of biosimilar mAbs
- What are the current factors while considering accessing a new market in Asia, apart from pricing and reimbursement?
- Role of patient groups and importance of patient-centric approaches – solving and shaping your access strategy
- How to address splintered regulatory fundament by overcoming regulatory hurdles?
- Is it possible to license by reciprocity in Asia?

**10:10 – Exploring ways to break into India's private market**

- How to point the fragmented reimbursement system and the price ceiling in India?
- What are the current demands on vaccines in India?
- How should companies price their drugs to be competitive in this market?
- What are the new accesses for consumer product? And how industries can expand their presence and sales in India?

**10:40 – Morning Coffee/Tea & Discussion**

## **CHALLENGES & OPPORTUNITIES**

**11:00 – DISCUSSION WITH EXPERTS: What is the future consideration for biosimilar and how is the biosimilar market formulating globally?**

- What is the recent approval for biosimilars sale in major market and how they made it?
- What are the terms of regulations and IP stands before biosimilars?
- How can India better establish itself in the global market?
- Future biosimilars trends: present global market condition and exposures
- India's latest biosimilars guidelines: Opportunities and threats to generics and innovation driven pharma
- Biosimilar development in clinical trials
- Focusing on the lifecycle development of control strategies for biosimilar products
- Comparability versus similarity: physician and patient perspectives on biosimilar uptake and when patients should be switched
- Salient differences between Indian guidelines and WHO or international Guidelines on Biosimilars

**Moderator:**

**Panellists:**

**ROSHAN PAWAR, Senior Medical Advisor, Oncology, Alkem Laboratories**

**RAVISHANKAR KASTURI, Vice President - Development & Manufacturing, Reliance Life Sciences**

**ANIL KUKREJA, Medical Director, Roche Pharmaceuticals**

**KARAN THAKKAR, Regional Clinical Site Lead, Pfizer**

**HEMANT ZAVERI, Associate Director in Clinical Development of Biosimilar, Dr. Reddy's Laboratories**

**11:50 – Biosimilar and Biobetters development**

- Biosimilar and biobetters development and clinical case studies
- Designing and conducting global clinical trials
- Designing clinical frameworks and using data to effectively showcase bio-similarity
- Opportunities in biobetters development
- The latest on demonstrating interchangeability

- Approaches to harmonizing immunogenicity testing

### **12:20 – Manufacturing biologics: How to prevent human errors using automation**

- Identifying prevalent human errors in manufacturing processes
- Exploring possible automation solutions to eradicate
- Analysis on productivity improvements
- How does increased automation change the role of humans?

### **12:50 - Networking luncheon**



**Afternoon Chair person**

**PRASHANT BODHE, Director, CliniSearch**

### **14:10 – DISCUSSION WITH EXPERTS: Biosimilars in India: What's next? Consideration for long term market sustainability and market access strategies, opportunities and commercial challenges**

- Key developments in India's market landscape in terms of investment volume, regulations, competition and initiated projects
- India is a highly rivalrous biosimilar market: How to address challenges in staying relevant and ahead of competition
- Distinguish suggestions to meet the possibilities and demands at the post marketing phase of a biosimilar
- Analyse the possibility of looking into commercialisation of biosimilars abroad, improvement of bio-betters and advanced

drugs; as well as what organizations, can anticipate while planning to venture into biosimilar development

- Ways to ensure long-run sustainability of the biosimilar manufacturer as a whole
- Streamlining approval and access for follow-on biologics
- Opportunities and challenges in bringing future biosimilars to market
- Case studies for biosimilars product from current market analysis

**Moderator:**

**PRASHANT BODHE, Director, CliniSearch**

**Panellists:**

**SRIVANI MUKKAMALA, Independent Consultant**

### **14:50 – Licensing, partnerships and strategic alliance management**

- How to value your biotech start-up
- What should you be looking for in your partners and how can you make your business more attractive to them?
- What makes a successful partnership?
- How do you meet your buy-side customers?
- Getting your pitching strategy right

### **15:20 – Afternoon Tea/Coffee**

### **15:40 – Safety & Risk Management System for Biosimilars**

- Key players in biosimilars environment - overview of the US, EU, Canada, Japan and China
- Regulatory framework for risk management
- Risk management system of innovators versus biosimilars
- Risk management strategies for biosimilars; concerns, uncertainties and future scope

**REGULATORY**

**16:10 – DISCUSSION WITH EXPERTS:  
Biosimilar regulations and development  
updates**

- Reducing gap between regulatory science and medical practice: Platforms & tools – that could inspire others to follow
- Regulatory science and medical practice: how to cut down the gaps
- Connecting the dots? Towards international regulatory convergence
- What are the key new international developments? What can we adapt from those?
- Strategies for improving regulatory expertise and cross-nation support for promoting regulatory policy innovation
- Examine current thinking from industry and regulators on requirements for post approval changes to biosimilar products
- Global harmonization in quality and regulatory requirements - are we on track?

**Moderator:**

**Panellists:**

**HANMANT BARKATE, Vice President & Head  
Medical affairs & Clinical Research,  
Wockhardt**

**ALAP GANDHI, Head, Medical Affairs, GSK**

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

**17:00 – 18:00 - Networking Drinks Session**

**Networking Drinks Reception**

Take your discussions further and build new relationships in a relaxed and informal setting.