



# 9th BIOSIMILARS Congregation 2016

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

22nd September 2016, The Lalit Hotel, Mumbai, India

## Key Speakers Include

**DHILEEP KRISHNAMURTHY**, Piramal Life Sciences,  
Vice President & Head Global R&D API

**BHASWAT CHAKRABORTY**, Cadila,  
Senior VP & Chair, Research and Development Core Committee

**ARUN BHATT**, Consultant - Clinical Research & Development

**PRITI THAKOR**, Merck,  
Associate Director Medical Affairs

**INDRANIL BHATTACHARYA**, Eli Lilly,  
Associate Director Medical Affairs

**ANINDITA DAS**, Dr. Reddy's Laboratories,  
Associate Director

**MANISH VERMA**, Sanofi,  
Director Medical Affairs

**DEBOLINA PARTAP**, Wockhardt,  
Associate Vice President and Head Legal

**PARIKSHIT CHAUDHARI**, Nestle,  
Medical Affairs Manager

**HANMANT BARKATE**, Intas Pharmaceuticals,  
VP & Head- Medical Services

**AMARDEEP UDESHI**, Cipla Biologicals,  
Head - Strategy and Market Assessment

**CHANDRA SEKHAR**, Reliance Life Sciences,  
Vice President Quality

**SAMBIT PATNAIK**, Clintech India,  
CEO & Medical Director

**KAVYA KADAM**, Cipla,  
Head- Global Clinical Operations

**SUNIT MAITY**, Theramyt Novobiologics,  
AVP - Product Development

**ANAY SHUKLA**, Nishith Desai Associates,  
Associate

**VARSHA NARAYANAN**, Wockhardt,  
Head Medical Affairs

**NIPOM DEKA**, Covance,  
Medical Director, Pharmacovigilance & Drug Safety

**SANKET SAWANT**, SIRO Clinpharm,  
Strategy & Business Development Partner

Plus many more...

## 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

### Book now...

Register now to secure your seats  
Call +91 44 64536444  
or  
email - [info@virtueinsight.com](mailto:info@virtueinsight.com)

Learn, Partner, Innovate,  
Succeed



9th Biosimilars Congregation 2016  
22nd September 2016, The Lalit Hotel, Mumbai, India

**SUPPORTED BY**



**ORGANIZED BY**



FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - [delegate@virtueinsight.com](mailto:delegate@virtueinsight.com)

FOR SPONSORSHIP OPPORTUNITIES:-

Sponsorship or exhibition is the best way to speed network with decision makers. The world leader speakers in our conferences attract niche delegates from all over the world. This would be a wonderful opportunity to reach the right audience and save money and time on all your other advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/newsletters about the event and advertise the event via different forms of media.

Sponsorship Enquires - [sponsor@virtueinsight.com](mailto:sponsor@virtueinsight.com)

# 9th Biosimilars Congregation 2016

## 22nd September 2016, The Lalit Hotel, Mumbai, India

### CONFERENCE INTRODUCTION:-

Virtue Insight invites you to the 9th Biosimilars Congregation 2016 during 22nd September 2016 Mumbai - India. This 9th Biosimilars Congregation 2016 brings together scientists, researchers and CROs from around the world. Biologics are a highly effective class of medicines that are based on naturally occurring proteins and produced using living cells. Current concepts of drugs and biologics, Unique considerations for biologics, Early clinical development essentials, Cancer therapeutics, Comparability for Biologics, Biosimilar approvals are the points of discussion in this session.

9th Biosimilars Congregation 2016 conference will bring together top pharmaceutical, biotechnology and regulatory representatives under one roof that will address the key issues of the industry. Hence, this global event will look at the multiple facets of biosimilars, ranging from the evolving regulatory landscapes, biosimilar guidelines to the legal and economic aspects and current challenges in biosimilar development. This biosimilar conference will focus on multiple aspects of biosimilar product development to successfully deliver safe, biosimilar products to the market place. By attending this biologics conference you will gain a comprehensive outlook on the key issues surrounding biosimilars. This event will provide an important platform for biosimilars stakeholders to discuss and share best practices in expediting development in Biosimilars 2016 and onwards.

### KEY THEMES DISCUSSED AT THIS CONFERENCE:-

- Global biopharma policy & market trends
- The future of biosimilars in India
- The evolving biosimilar sector: Trends and Implications
- Complex biological models in biosimilar development
- Viable extrapolation strategies for biosimilars with special emphasis on TNF antagonists
- Effectively communicate the value of biosimilar products to raise confidence in the class
- Improving characterization of biosimilars with technology
- Create a robust patient services and reimbursement support program for biosimilar products
- The future of the biosimilar industry - mapping the evolution and development of the biosimilar sector
- Forecasting the financial growth of biosimilars in the global healthcare marketplace
- Planning of a biosimilar development project - what to consider from the very beginning
- Clinical development strategies for biosimilars
- Gaining Better Market Access: Is Commercial CMO Acceptable for the Biosimilars Market?
- Regulatory Updates and Development
- Be part of a major networking opportunity

### 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/ Biogenerics, 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

# 9th Biosimilars Congregation 2016

## 22nd September 2016, The Lalit Hotel, Mumbai, India

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

**09:30 – Chairperson opening remarks**

**SUNIT MAITY**, AVP - Product Development, **Theramyt Novobiologics**

### MARKET OVERVIEW & ANALYSIS

**09:40 – Regulatory challenges – Global vs. Local**

- Differences between approach of new FDA and Indian regulation
- Challenge of establishing biosimilarity
- Focus on clinical efficacy vs. activity

**ARUN BHATT**, Consultant – Clinical Research & Development

**10:10 – The future of biosimilars in India**

- Establishing R&D capabilities within India vs. maximizing commercial opportunities
- Building local expertise and talent pools for the future
- Beefing up innovative and lean manufacturing facilities for biosimilars
- How is the interest and competitions affecting market entry?

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

### CHALLENGES & OPPORTUNITIES

**11:00 – DISCUSSION WITH EXPERTS: The evolving biosimilar sector: Trends and Implications**

- What are the myths and realities about biosimilars in Asia?
- How can we increase understanding of biosimilars among physicians, patients, and other key stakeholders?
- Why do biosimilars require a paradigm shift in our approach to evaluating clinical data?
- How might the emerging global trends with payers and regulators shape biosimilar development and commercialization?
- Understanding the challenges and opportunities that face biosimilar clinical development
- Planning of a biosimilar development project - what to consider from the very beginning
- How is biosimilars uptake in the market encouraged?

**Moderator:**

**Panellists:**

**PRITI THAKOR**, Associate Director Medical Affairs, **Merck**

**DHILEEP KRISHNAMURTHY**, Vice President & Head Global R&D API, **Piramal Life Sciences**

**ANINDITA DAS**, Associate Director, **Dr. Reddy's Laboratories**

**PARIKSHIT CHAUDHARI**, Medical Affairs Manager, **Nestle**

**11:40 – Complex biological models in biosimilar development**

- Determining risk of anaphylaxis, autoimmunity, and anti-drug antibodies
- Assessing impact of subtle recognized differences in quality attributes extrapolated over time, and across a heterogeneous population
- Exploring the utility of models in the science of comparison in the context of difficult challenges in biosimilar development

**12:10 – Viable extrapolation strategies for biosimilars with special emphasis on TNF antagonists**

- Analogies between comparability and similarity exercises
- Similarity across different modes of action: Preclinical support
- Most sensitive study populations for extrapolation of clinical performance
- Beyond the regulator's blessing: Physicians', patients', payers' view

**12:40 – Networking luncheon**

**Afternoon Chair person**

**14:00 – DISCUSSION WITH EXPERTS: Effectively communicate the value of biosimilar products to raise confidence in the class**

- Learn what approaches large innovators are taking and whether smaller manufacturers should follow suit
- Explore whether price points are sufficient or if other determinants need to be articulated
- Identify long-term branding, promotion, and marketing investments that will have the most impact on commercial success
- Develop strategic partnerships for global biosimilar business development
- Identify the opportunities and considerations of strategic partnering to design a successful strategy
- Articulate the distinctions between partnerships across the U.S., other advanced economies, and emerging markets (RoW)
- Understand the impact of increased licensing and acquisition of biotech products by larger pharmaceutical companies
- Successful biosimilar product case studies from bench top to market

# 9th Biosimilars Congregation 2016

## 22nd September 2016, The Lalit Hotel, Mumbai, India

### Moderator:

**SAMBIT PATNAIK**, CEO & Medical Director, **Clintech India**

### Panellists:

**AMARDEEP UDESHI**, Head – Strategy and Market Assessment, **Cipla Biologicals**

**NIPOM DEKA**, Medical Director, Pharmacovigilance & Drug Safety, **Covance**

**VARSHA NARAYANAN**, Head Medical Affairs, **Wockhardt**

**BHASWAT CHAKRABORTY**, Senior VP & Chair, Research and Development Core Committee, **Cadila**

**SANKET SAWANT**, Strategy & Business Development Partner, **SIRO Clinpharm**

### 14:50 – Corporate strategies to develop biosimilars

- Challenges in developing Biosimilars
- Elements of robust R&D performance strategies
- International and Indian Guidelines
- Biosimilar development case studies

**BHASWAT CHAKRABORTY**, Senior VP & Chair, Research and Development Core Committee, **Cadila**

### 15:20 – Afternoon Tea/Coffee

### 15:40 – Data integrity compliance & successful inspections

- Importance of Data Integrity
- Quality by Design (QbD)
- Effective CAPA (Corrective Preventive Action)
- Role of Quality Metrics

**CHANDRA SEKHAR**, Vice President Quality, **Reliance Life Sciences**

## REGULATORY

### 16:10 – DISCUSSION WITH EXPERTS: Regulatory updates and development

- Updates on biosimilar and biobetters regulatory guidelines
- What are some peculiarities of the regulatory pathway in India?
- Streamlining approval and access for follow-on biologics
- The future of the biosimilar industry - mapping the evolution and development of the biosimilar sector
- Review and approval speed of FDA – is that now a concern?
- How cGMP guidelines have been implicated in real time operation, not during audition

- Manufacturing sciences
  - GMP compliant manufacturing facility in India
  - Operation excellence and improvement
  - Product quality: how quality is evaluated by manufacturers?
- Managing higher volumes and larger amounts clinical trial data

### Moderator:

**ANAY SHUKLA**, Associate, **Nishith Desai Associates**

### Panellists:

**MANISH VERMA**, Director Medical Affairs, **Sanofi**

**DEBOLINA PARTAP**, Associate Vice President and Head Legal, **Wockhardt**

**KAVYA KADAM**, Head- Global Clinical Operations, **Cipla**

**HANMANT BARKATE**, VP & Head- Medical Services, **Intas Pharmaceuticals**

**INDRANIL BHATTACHARYA**, Associate Director Medical Affairs, **Eli Lilly**

### 16:50 – Chairperson’s closing remarks and end of conference

17:00 - 18:00 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting



# 9th Biosimilars Congregation 2016

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



REGISTRATION  
DESK

Coffee / Tea / Networking Area

1

4

2

5

3

6

# Partial list of attendees from our previous Biosimilars Congregation

3P Biopharmaceuticals  
AB SCIEX  
Abbott  
Abbvie  
Abdi Ibrahim  
Accelera srl  
Accutest Research Laboratories  
Actavis Biologics  
Akumentis Healthcare  
Albany Molecular Research  
Alembic Pharmaceuticals  
Alkem Laboratories  
Alkem Labs  
Amgen  
Antitope  
APM Health Europe  
appliedstrategic  
Arnold & Porter LLP  
Atheln, Inc  
AURA Biotechnologies  
Avra Synthesis  
Baxter Healthcare  
Bayer Pharma  
Beyond Antibody  
Bilcare GCS  
Bilcare Research  
Bio Med Talk  
Bio Pharma Insight  
BioAgilytix Labs  
BioFrontline  
Biogen IDEC  
BioGenomics  
BioKinetic Europe  
Bionees  
BioOutsource  
BioProcess Technology Consultants  
Biosimilar News  
Biosimilars Licensing  
Bioton S.A.  
BioXpress Therapeutics  
Bird & Bird  
Bloomberg News  
Boehringer Ingelheim  
BofA Merrill Lynch  
Bristol Myers Squibb  
Bristows  
Broughton Laboratories  
Business Vibes  
Business Wire  
Cadila Pharmaceuticals  
Cambridge Healthcare & Biotech  
Caprion Proteomics  
Catalent Pharma Solutions  
Celltrion  
Chemical Weekly  
Cinfa Biotech  
Cipla Biologicals  
Clinigen CTS  
Clinsoft Clinical Research  
Clintech India  
CMC Biologicals  
Conference Locate  
Covance Laboratories  
Crystal Clear Conferences  
D2L Pharma Research Solutions  
Daewoong Pharmaceutical  
DASGIP Information and Process Technology  
Datamonitor Healthcare Consulting  
Denka Seiken  
Domainex  
Dong A Pharmaceutical  
Dr. Reddy's  
DRG  
DSM Biologicals  
Dutch Health Care Inspectorate  
EBTC  
Ecron Acunova  
Eli Lilly  
Ellis Pharma  
Embio  
EPIRUS Biopharmaceuticals  
ERA Consulting  
Ethicare Clinical Trial Services  
Euro Diagnostica  
Eurofins Lancaster Laboratories  
Evidera  
Evonik India  
FirstWord  
Fisher Clinical Services  
FlandersBio  
Formycon AG  
Frontline Pharma  
Frontline Pharma  
Frontline Pharma Consulting Ltd  
Frost & Sullivan  
Genotypic Technology  
Glenmark Generics  
GNH India  
Going to Meet  
Good Clinical Practice Alliance – Europe (GCPA)  
GSK  
GSS HR Solutions  
Healthcare at Home  
Herbert Smith Freehills LLP  
Himedia Laboratories  
Hisut  
Hospira  
Huntingdon Life Sciences  
HYPERMARCAS  
ICON Clinical Research  
IDDI  
IDT Biologika GmbH  
IGATE Global Solutions  
IMS Health  
INC Research  
Infinata, Inc  
Innovaro  
INSERM  
InSight Biopharmaceuticals  
Intas Pharmaceuticals  
Interpharm Consultancy  
IPPro Lifesciences  
ISU Abxis  
Jakob & Partners  
Janssen Biologics B.V.  
JHL Biotech  
Johnson & Johnson  
KEYPHARMA PLG  
Lambda Therapeutic Research  
LEO Pharma  
Lupin  
Lupin Limited (Biotech Division)  
Luther Pendragon  
M. J. Biopharm  
Macleods Pharmaceuticals  
Makovsky & Co  
Markets&Markets  
Max Neeman  
Medac  
medac GmbH  
Medidata Solutions  
Mega Lifesciences  
Megafine Pharma  
Menarini Biotech Srl  
Merck Group  
Merck Millipore  
Merck Millipore - Bioscience  
Merck Serono  
MHRA  
Micro Therapeutic Research  
Minapharm Pharmaceuticals  
Mitsubishi Chemical  
MSD  
Mylan Healthcare GmbH  
Mylan Hospital & Retail  
Myoderm  
Napp Pharmaceuticals  
National Facility for Biopharmaceuticals  
NDA Regulatory Advisory Board  
Nishith Desai Associates  
Norweigen Medicines Agency  
Novartis Healthcare  
Nuvisan gmph  
Oasthouse Consulting  
OCT  
Olam International  
Omnicare Pharma  
ORION Clinical Services  
PAREXEL International  
Patheon  
PDP Life Science Logistics  
PerkinElmer  
Petra Drug Store  
Pfizer  
Pfizer-Hospira  
Pharma Mirror  
Pharma Voice  
Pharmaceutical Consultant  
Pharmaleaf  
Pharmaphorum  
Pharmcast  
Pharminvent  
Pharm-Olam International  
PharmSource Information Services  
PIONEERA HealthCare Group  
PPD  
PPI  
Prediction BioSciences  
Prescient Lifesciences  
Protagen Protein Services  
QPS Holdings LLC  
Quantimmune Solutions  
Quest Diagnostics  
Quintiles  
Ranbaxy Laboratories  
RAS LSS  
REGEM Consulting  
Reliance Life Sciences  
Richter Helm Biotec  
Roche AB  
Roche Products  
R-PHARM  
RSA  
SACHEM, Inc  
SAI MedPartners  
Sandoz Biopharmaceuticals  
Sanofi Aventis Group  
Sanofi India  
SCIEX Separations  
SCM Pharma  
Scrip Intelligence  
Serbia-Alims  
SGS M-Scan  
Sidley Austin  
SIES College of Management Studies  
SIRO Clinpharm  
SmartAnalyst  
Spectrum Regulatory Solutions  
Stragen Pharma SA  
Sun Pharmaceutical Industries  
Syngene International  
Takeda Pharmaceuticals  
Tata Consultancy Services  
Teva Pharmaceuticals  
The Council of EU Chambers of Commerce in India  
The Economic Times  
The Wall Street Journal  
Thermo Fisher Scientific  
Thompson Media Group  
TikhePharma  
Triskel Integrated Services  
UBC  
UCL Hospitals NHS Trust, University of London  
Unichem  
United States Pharmacopeia India  
Vela Labs GmbH  
ViaTAL Pharma Consulting  
Vifor Pharma  
Vigi Medsafe  
Viridisgroup  
Voisin Consulting Life Sciences  
West Pharmaceutical Services  
Witness Magazine  
Wockhardt  
Woodley BioReg  
World Courier  
Worldwide Clinical Trials  
Yakumed  
Zelle Biotechnology  
Zydus Cadila

# REGISTRATION FORM

## RESERVATION PRICING:

### Early Bird Discount Rate Till 09th August 2016

1 day conference per delegate - Fee: INR 06,000 + Tax

### Standard Rate (From 10th August 2016)

1 or 2 delegates - per delegate - Fee: INR 07,000 + Tax

### Group Discounts

3 or 4 delegates - per delegate - Fee: INR 06,500 + Tax

### Group Discounts

For 5 and above delegates - per delegate - Fee: INR 05,500 + Tax

### Spot Registration:-

1 Day conference per delegate - Fee: INR 08,000 + Tax

## Registration Form Details:

Forename .....Surname .....

Job Title .....Company .....

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 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](mailto:info@virtueinsight.com)  
Web: <http://www.virtueinsight.com>  
India Office: Tel: +91 44 64536444

### General information Venue:

The Lalit Hotel  
Sahar Airport Road, Andheri East,  
Opp. Hotel Leela,  
Mumbai 400059 - India  
Tel: 91 22 6699 2222

### 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 refund your registration fee and we will try to 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

