



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

PRANJAL BORDOLOI, Veeda Clinical Research,
AVP - Medical Affairs and Pharmacovigilance

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

Learn, Partner, Innovate,
Succeed



9th Biosimilars Congregation 2016
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EXHIBITOR



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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

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

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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

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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:

PRANJAL BORDOLOI, AVP - Medical Affairs and Pharmacovigilance, **Veeda Clinical Research**

Panellists:

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

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

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

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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
- Managing the QbD paradigm: manufacturing of biotech therapeutics

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**

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

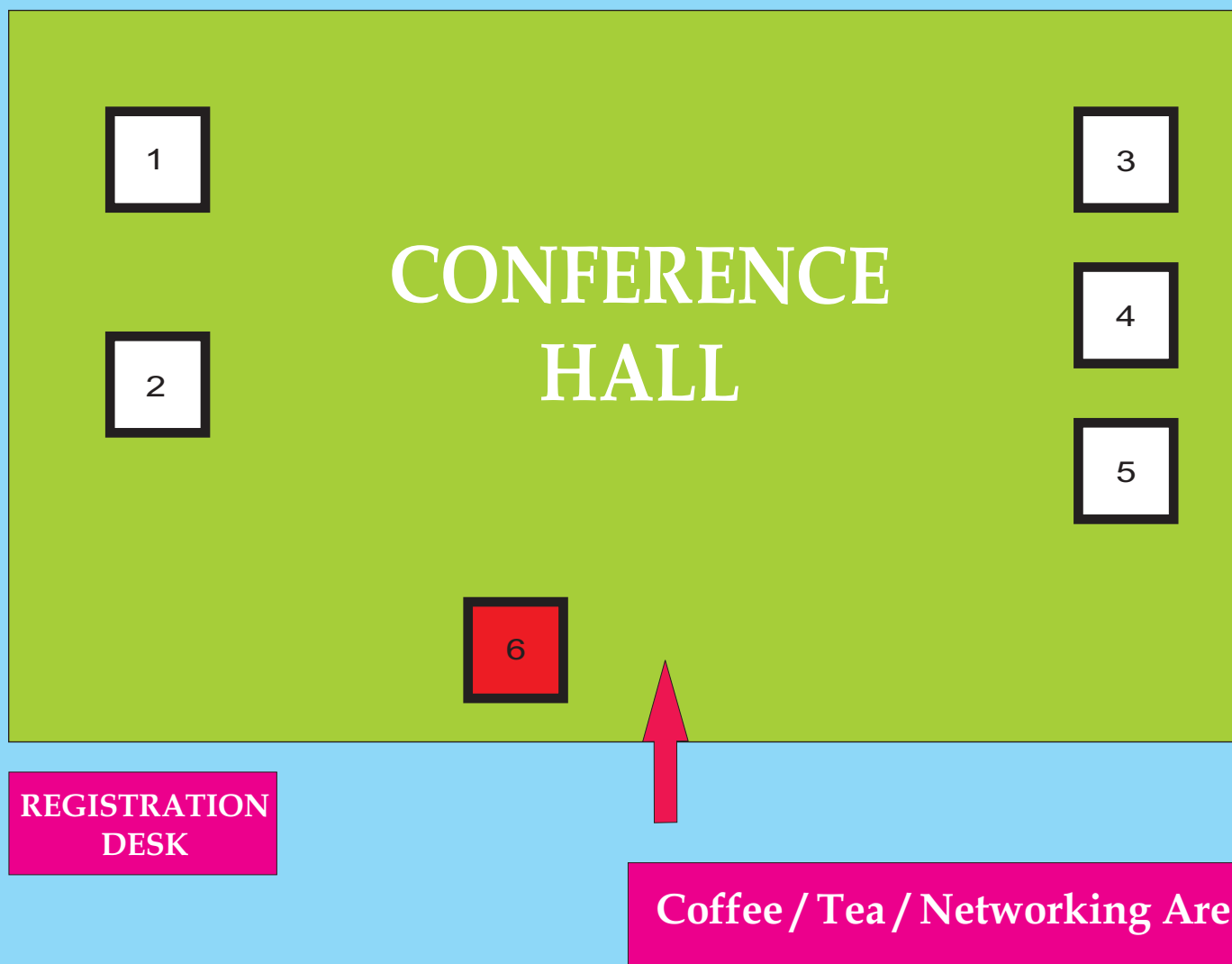
16:50 – Chairperson's closing remarks and end of conference

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 !!!



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Partial list of attendees from our previous Biosimilars Congregation

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

ForenameSurname

Job TitleCompany

Official Contact Number

Address

CountryPostcode.....

PhoneFax

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

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 ☐



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