CONFERENCE TOPICS

Pre-Conference Workshops:
- Essentials of Medical and Regulatory Writing
- Overview of Global Medical Device Regulations
- Clinical Trial Designs, Conduct and Review: An FDA Perspective
- Regulatory Policy Roundtable
- Update on Global Regulatory Landscape

Drug Discovery
- Quality
- Pharmacology and Toxicology

Development of Biologics
- Clinical Trials
- Pharmacovigilance
- Biopharmaceutics
- Bioinformatics and Data Management
- Combination Products
- Drug Delivery
- Value Proposition in Clinical Research
- Regulatory

FEATURED SPEAKERS

Prof. V. Nagaraja, PhD
Chairman, Microbiology and Cell Biology, Indian Institute of Science

Timothy Cote, MD
Director, Office of Orphan Products Development, FDA

Agnes Saint-Raymond, MD
Secretary, Department of Pharmaceuticals, Government of India

Prof. Umesh Varshney, PhD
Head, Biologicals and Biotechnology, IIT-Kanpur, UK

Gopalan Narayanan, MD
Head, Biologicals and Biotechnology, MHRA, UK

Ashok Kumar
Secretary, Department of Pharmaceuticals, Government of India

John Ballan, MD
Senior Vice President, Bristol-Myers Squibb, USA

STEPHEN E. WILSON, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

Committee:
- KIRAN MARATHAK, MD
  Director, Veeda Clinical Research (Pvt.) Ltd.
- MUNISH MEHRA, PhD
  Managing Director, Global Drug Development Experts, USA
- MEHUL MEHTA, PhD
  Director, Division of Clinical Pharmacology, OCP, OTS, CDER, FDA, USA
- GOPALAN NARAYANAN, MD, FRCP, MFPM
  Manager and Head, Biologicals and Biotechnology, Medicines and Healthcare Products Regulatory Agency (MHRA), UK
- FERNANDO QUEZADA, MPA
  Executive Director, Biotechnology Center of Excellence, Corporation, USA
- DEVEN PARMAR, MD
  Vice President, Clinical Research, Wockhardt Ltd.
- PROFESSOR VINOD RAINA, MD
  Head, Medical Oncology, All India Institute of Medical Sciences, New Delhi
- RUCHIKA RAWAL, MS, RAC
  Global Pharmaceutical Regulations, California and Bangalore
- VIBHAKAR SHAH, PhD
  Senior Policy Advisor, Division of Manufacturing and Product Quality, OC, CDER, FDA, USA
- DEEPTI SANGHAVI, BHMS, PGDCR
  Lecturer, Clinical Research Education and Management Academy (CREMA), India

Scientific Advisory Board:
- PROFESSOR SURESH K. GUPTA, PhD, DSc
  Dean & Director General, Institute of Clinical Research (India)
- NANDINI KUMAR, MBBS, DCP, MHSc (Bioethics)
  Consultant, Indian Council of Medical Research, New Delhi
- NARGES MAHALUXMIVALA, MD
  Consultant, formerly Senior Advisor, Clinical Development Services, Quintiles India
- PROFESSOR SHIRLEY MURPHY, MD
  Professor Emeritus, University of New Mexico School of Medicine, Albuquerque and formerly Director, Office of Translational Sciences, CDER, FDA, USA
- PREM K. NARANG, PhD
  Vice President, Head-Global Regulatory Affairs, MedicaLogic, General Electric, USA
- SUPRIYA SHARMA, MD, MPH, FRCPC
  Director General, Therapeutic Products Directorate, Health Canada
- KIRAN MAZUMDAR SHAW
  Chairman and Managing Director, Biocon
  Founder Entrepreneur
- TIMOTHY COTE, MD
  Director, Office of Orphan Products Development, FDA

Conference:
- 4th Annual Conference on Drug Discovery and Clinical Development in India
- Scientific and Regulatory Advances across Borders
- November 16-18, 2009 Tutorials: November 15
- Hotel Sheraton, Saket, New Delhi, INDIA

Contact Information:
- Kanchan Patel, Phone: +022 6741 7625, Email: Kanchan.Patel@diaindia.org
- Vinisha Bhavsar, Phone: +022 6765 3226, Email: dia.diaindia@gmail.com
DAY 1 | SUNDAY, NOVEMBER 15

8:00 AM-7:00 PM  CONFERENCE REGISTRATION
Hotel Sheraton
New Delhi, India

8:00-9:00 AM  WORKSHOP REGISTRATION
Hotel Sheraton
New Delhi, India

9:00 AM-1:00 PM  TUTORIAL WORKSHOPS #1 AND #2
#1 Essentials of Medical and Regulatory Writing
Professor Suresh K. Gupta, PhD, DSc
Director General, Institute of Clinical Research (India),
(Chairman)
Uma Sharma, PhD
Chief Scientific Officer
MMS Holdings, Inc., Canton, Michigan, USA
Dr. Siddarth S. Chachad
Medical and Safety Expert, Cipla Ltd, India
Nimita Limaye, PhD
SIRO, India

#2 Overview of Global Medical Device Regulations
Ruchika Raval, MS, RAC (Coordinator)
Global Pharmaceutical Regulations, California and Bengaluru
Enrico Ruhle
Managing Director
TÜV Rheinland (India) Pvt. Ltd., Bangalore, India

1:00-5:00 PM  TUTORIAL WORKSHOPS #3 AND #4
#3 Clinical Trial Designs, Conduct and Review:
An FDA Perspective
Stephen E. Wilson, DrPH, CAPT. USPHS (Coordinator)
Director, Division of Biometrics III
CDER, FDA, USA

#4 Regulatory Policy Roundtable
Satish C. Tripathi, PhD, RAC (Coordinator)
President
Biomedical Consulting International, Inc.
Chicago - Mumbai - New York
Fernando Quezada, MPA (Facilitator)
Executive Director
Biotechnology Center of Excellence Corporation
Boston, Massachusetts, USA

DAY 2 | MONDAY, NOVEMBER 16

8:45-9:05 AM  SPECIAL ADDRESS
Ashok Kumar
Secretary, Department of Pharmaceuticals
Government of India

9:05-9:15 AM  SESSION I — OPENING REMARKS
Satish C. Tripathi, PhD, RAC
Chair for Scientific Advisory Board and Program Committee
President
Biomedical Consulting International, Inc.
Chicago - Mumbai - New York

9:15-10:00 AM  SESSION II — KEYNOTE ADDRESS
Opportunities for Discovery Research in India
Professor Umesh Varshney, PhD
Microbiology and Cell Biology Laboratory
Indian Institute of Science, Bangalore, India

10:00-10:30 AM  SESSION III: SPECIAL LECTURE
ICMR and Its Catalytic Role in the Development of
Clinical and Regulatory Policy: Vision for 2020
Dr. S. D. Seth
Pharmacology Expert, Formerly Chairman, Clinical Pharmacology
Indian Council of Medical Research, New Delhi, India
Vijay Kumar, PhD
Scientist F, Division of Basic Medical Sciences
Organizer, Committee for Review of IND Application
for DCGI Office
Indian Council of Medical Research, New Delhi

10:30-11:00 AM  REFRESHMENT BREAK

11:00-11:30 AM  SESSION IV
R&D Strategy: Value Creation through Strategic
Partnerships
Mahesh Singh
Managing Director
PRTM India, Bangalore

11:30 AM-12:00 PM  SESSION V — KEYNOTE ADDRESS
From Basic Biology to Drug Discovery Efforts –
An Ongoing Journey
Professor V. Nagaraja
Chairman
Department of Microbiology and Cell Biology
Indian Institute of Science, Bangalore

12:00-12:45 PM  SESSION VI — SPECIAL LECTURE
Recent Developments at Indian Pharmacopoeia
Commission and Its Activities over the Next 5-10 Years
Dr. G. N. Singh
Scientific Director
Indian Pharmacopoeia Commission

12:45-1:45 PM  NETWORKING LUNCHEON
1:45-3:45 PM  SESSION VII
Update on Global Regulatory Landscape – Regulatory Strategic Discussion with Global Regulatory Leaders (Invitees: FDA, EMEA, and MHRA)
SESSION CHAIRPERSON
Satish C. Tripathi, PhD, RAC
President
Biomedical Consulting International, Inc.
Chicago – Mumbai – New York
Areas to be covered: Healthcare Reforms, Comparative Effectiveness, Inter-Governmental Relationships, Biosimilars, Electronic Data Capture, Digitalization of Health Records, Pandemic H1N1 issues

EMEA
Dr. Agnes Saint-Raymond
Head, Scientific Advice & Orphan Drugs Sector, Pediatric Medicinal Products (SAOD)

FDA
Timothy Cote, MD
Director, Office of Orphan Products Development
Office of Commissioner

David Jacobson Kram, PhD
Associate Director and Head
Pharmacology-Toxicology, CDER

Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCS, OTS, CDER

Stephen Wilson, PhD
Director, Division of Biometrics III, CDER

MHRA
Gopalan Narayanan, MD
Manager and Head, Biologicals and Biotechnology

3:45-4:00 PM  REFRESHMENT BREAK

4:00-5:00 PM  SESSION VIII
Recent Developments in Translational Research
SESSION CHAIR
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCS, OTS
CDER, FDA, USA

Translational Research Opportunities in India
Sudhir Borgonha
Saint John’s Medical College Hospital, Bangalore, India

FDA Activities in Translational Research
Mehul Mehta, PhD

5:00-5:30 PM  SESSION IX
Scientific Challenges of Regulated Bioanalysis During Development of Generic and Innovative Drug Molecules
Mohinder Bathala, PhD
Daichi-Sankyo, USA

5:30-6:00 PM  SESSION X
Preparing Project Managers for “Full Service” Clinical Trials
Mubarak Naqvi, MD
Vice President, Project Management and Client Services
CliniRx Research Pvt. Ltd, Gurgaon, India

6:15-9:45 PM  NETWORKING RECEPTION AND DINNER

DAY 3 | TUESDAY, NOVEMBER 17
8:00-9:00 AM  REGISTRATION

9:00-9:05 AM  WELCOME
Kiran Marthak, MD
Director
Veeda Clinical Research (Pvt.) Ltd., Ahmadabad, India

9:05-9:15 AM  SESSION XI
Opening Remarks
Narges Mahaluxmivala, MD
Physician Consultant and formerly Senior Advisor, Clinical Development Services
Quintiles India

9:15-10:00 AM  SESSION XII: KEYNOTE ADDRESS
Orphan Drug Development: FDA Incentives and Opportunities for Biopharmaceutic Industry
Timothy Cote, MD
Director, Office of Orphan Products Development
Office of the Commissioner
FDA, USA

10:00-10:30 AM  SESSION XIII
Role of Biopharmaceutical Classification Systems (BCS) in Drug Development
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCS, OTS
CDER, FDA, USA

10:30-10:45 AM  REFRESHMENT BREAK

10:45-11:15 AM  SESSION XIV
International AIDS Vaccine Initiative – Path to AIDS Vaccine Development in India
Solani Kochhar, MD
Medical Director, International AIDS Vaccine Initiative, New Delhi

11:15 AM-11:45 PM  SESSION XV
Regulatory Pathways for Registering Drugs in the United States: How Can Indian Companies Benefit?
Satish C. Tripathi, PhD, RAC
President
Biomedical Consulting International, Inc.
Chicago - Mumbai – New York

11:45 AM-1:15 PM  SESSION XVI
Regulatory Considerations for Registration of New Drugs In Latin America, Central Asia and Middle East
SESSION CHAIRPERSON
Fernando Quezada, MPA
Executive Director
Biotechnology Center of Excellence Corporation
Boston, Massachusetts, USA

1:15-2:00 PM  LUNCHEON AND ROOM CHANGE
This session will review the current regulatory situation in the countries of Intercontinental Regions. Increased capacity for clinical trials and other infrastructure considerations will be discussed along with comparative observations.

**Drug Registration and Clinical Trials in the Next 11 Countries**
Romi Singh, PhD  
Executive Director, International Regulatory, Amgen, USA

**Drug Lags and Simultaneous Global Development in Key Emerging Countries**
Arun Mishra, PhD  
Global Regulatory Strategy, Pfizer, Inc., Sandwich, UK

**Clinical Development Plans in Asia: Regulatory Strategy and Tactical Implementation**
Chet Elias  
Director, International Regulatory  
Amgen, USA

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**CONCURRENT SESSION XVII – PARALLEL SESSIONS**

**Concurrent Session XVII-A**
Can India Unlock the Potential for Worldwide Availability of Biosimilars?

**SESSION CHAIRPERSON**
Gopalan Narayanan, MD  
Manager and Head, Biologicals and Biotechnology  
MHRA, London, UK

- **Introduction: Overview of Biosimilars**
  Gopalan Narayanan, MD

- **EU Guidelines and Experience; Nonclinical and Early Clinical Development**
  Emmanuelle Voisin, PhD  
  Voisin Consulting, Paris, France

- **How to Ensure Drug Products are (Bio) Similar: Manufacturing Aspects**
  Ajaz Husain, PhD  
  Vice President, Biological Systems  
  PMI Global Services, Inc., Washington, DC, USA

- **Financial Implications for India and Beyond**
  Deven Parmar, MD  
  Vice President, Clinical Research  
  Wockhardt, Mumbai, India

- **Regulatory and Scientific Developments Outside EU**
  Ajaz Husain, PhD (Americas)  
  Deven Parmar, MD (WHO, ROW)

**Concurrent Session XVII-B – BIOETHICS: DEBATE**
Proposition: Placebo Usage Should be Discouraged in Clinical Trials Conducted in Emerging Countries

**MODERATOR**
Arun Bhatt, MD  
Clininvent Research  
Mumbai, India

- **For the Proposition:**
  R. Nagpal, MD  
  Consultant Neuro-Psychiatrist  
  New Delhi, India

  C. S. Potkar, MD  
  Pfizer India, Mumbai

- **Against the Proposition:**
  Shoibal Mukerjee, MD  
  GVK Bio, New Delhi, India

  Nandini Kumar, MBBS, DCP, MHSc (Bioethics)  
  Consultant, Indian Council of Medical Research, New Delhi, India

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**SESSION XVIII**
India’s Potential in Developing Drugs for Rare and Neglected Diseases: Clinical and Regulatory Considerations

**SESSION CHAIRPERSONS**
Yves Champey, MD  
former Chairman, Drugs for Neglected Diseases Initiative (DNDi), France

Fernando Quezada, MPA  
Executive Director, Biotechnology Center of Excellence Corporation, USA

This session brings attention to the needs and opportunities associated with drug development for neglected diseases. Speakers will describe the current challenges associated with innovation in this area and opportunities for India to expand and diversify its contributions in this area.
DAY 4 | WEDNESDAY, NOVEMBER 18

7:30-9:00 AM  REGISTRATION

9:00-9:05 AM  WELCOME
Deepti Sanghavi, BHMS, PGDCR
Lecturer
Clinical Research Education and Management Academy (CREMA), Mumbai

9:05-9:15 AM  SESSION XIX
Opening Remarks
Nandini Kumar, MBBS, DCP, MHSc (Bioethics)
Consultant
Indian Council of Medical Research, New Delhi

9:15-9:45 AM  SESSION XX – KEYNOTE ADDRESS
Global Approach to Pediatric Drug Development
Dr. Agnes Saint-Raymond
Head, Scientific Advice & Orphan Drugs Sector, Pediatric Medicinal Products (SAOD), EMEA

9:45–10:15 AM  REFRESHMENT BREAK

10:15–11:15 AM  SESSION XXI
Next Generation Pharmacovigilance
SESSION CHAIR
John Balian, MD
Senior Vice President, Global Pharmacovigilance and Epidemiology Research and Development
Bristol-Myers Squibb, USA

- The Next Generation Pharmacovigilance – An Innovative Model to Enhance Patient Safety
  Valerie Perentesis, PharmD
  Executive Director, Global Pharmacovigilance and Epidemiology
  Bristol-Myers Squibb, USA

- Pharmacovigilance: An Indian Perspective
  Jabeen Menzies
  Pharmacovigilance Department
  Quintiles, Mumbai, India

11:15–11:45 AM  SPECIAL LECTURE
Safety Update from the International Conference on Harmonization
David Jacobson Kram, PhD
Associate Director and Head
Pharmacology-Toxicology
CDER, FDA, USA

11:45 AM–12:15 PM  SESSION XXII
Engaging with Regulators During Drug Development: Current Status and Recommendations for the Future
Uma Sharma, PhD
Chief Scientific Officer
MMS Holdings, Inc., Canton, Michigan, USA

12:15-1:00 PM  NETWORKING LUNCHEON

1:00-3:30 PM  SESSION XXIII
Clinical Operations and Monitoring
SESSION CHAIRPERSON
Munish Mehra, PhD
Managing Director
Global Drug Development Experts, USA

- Cultivating Successful Trial Conduct in Research-Naïve Centers
  Karen Raudibaugh
  Senior Director, Clinical Operations
  Auxilium Pharmaceuticals, Malvern, PA, USA

- Maximizing Indian Investigational Site’s Potential in Conducting Clinical Trials
  Munish Mehra, PhD

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  Karen Raudibaugh
  Senior Director, Clinical Operations
  Auxilium Pharmaceuticals, Malvern, PA, USA

- Maximizing Indian Investigational Site’s Potential in Conducting Clinical Trials
  Munish Mehra, PhD

3:30-3:45 PM  REFRESHMENT BREAK

3:45-4:15 PM  SESSION XXIV
Evolving Role of FDA India Office: An Update
Bruss Ross, PhD
Director, FDA
Embassy of the United States
New Delhi

Albinus D’Sa, PhD
Deputy Director, FDA
Embassy of the United States
New Delhi

4:15-4:30 PM  SESSION XXV
Closing Remarks
Satish C. Tripathi, PhD, RAC
Chair for Scientific Advisory Board and Program Committee
President
Biomedical Consulting International, Inc.
Chicago – Mumbai – New York

4:30 PM  CONFERENCE ADJOURNED
**TRAVEL AND HOTEL**  
Sheraton New Delhi Hotel, located in the business district and adjacent to the city centre of South Delhi, is also in close proximity to the Max International Healthcare Hospital and Apollo Hospital. The hotel is an easy 20-minute drive from the domestic/international airport, and 30 minutes from some of Delhi's largest convention centers such as Pragati Maidan and India Expo Centre. Attendees should make airline reservations as soon as possible to ensure availability. From Delhi Railway Station, the Hotel is located 22 Km. Sheraton New Delhi is holding a block of rooms at a reduced rate until October 10, 2009. Room availability at this rate is guaranteed only until the block is filled.

**Contact Information:**  
Sheraton New Delhi Hotel, District Center, Saket, New Delhi-110017  
India Contact: Ms. Ishu Sachdeva  
Phone: +911142661212 Fax: +911142662112  
Email: reservations.sheratonnewdelhi@itcwelcomgroup.in.  
Pls cc: owestadmin@itcwelcomgroup.in as well.

**CANCELLATION POLICY:** On or before NOVEMBER 1, 2009  
Cancellations must be in writing and be received by November 1, 2009. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. If the event is cancelled, the organizers are not responsible for any airfare, hotel or other costs incurred by registrants.

Upon cancellation, the administrative fee that will be withheld from refund amount is:  
FULL MEETING CANCELLATION (All refunds will be issued in the currency of original payment):  
Standard = INR 3,000 • Academia/Government = INR 2,000 • Tutorial = INR 1,000 • Student = INR 500

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4th Annual Conference on Drug Discovery and Clinical Development in India  
Scientific and Regulatory Advances Across Borders  
Meeting I.D. # 09953 – November 15-18, 2009 – The Sheraton New Delhi Hotel, Saket, New Delhi, INDIA

**Registration Fees**  
Registration fee includes refreshment breaks and luncheons and will be accepted by mail, fax, or online.

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**Tutorial Fees – Sunday, November 15**

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- Mr.
- Ms.

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**First Name**

**Job Title**

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