

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



PROGRAM COMMITTEE

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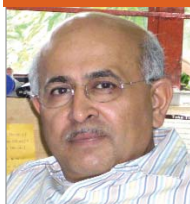
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SATISH C. TRIPATHI, PhD, RAC

President, Biomedical Consulting International, Inc.
Chicago - New York - Mumbai

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
Head, Orphan Drugs and
Pediatrics, EMEA



Prof Umesh Varshney, PhD
Microbiology and Cell
Biology, Indian Institute
of Science



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



Ashok Kumar
Secretary, Department
of Pharmaceuticals,
Government of India



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



**Stephen E. Wilson, DrPH,
CAPT. USPHS**
Director, Division of
Biometrics III, CDER, FDA

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

CONTACT INFORMATION

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Regional Offices

Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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),
(Coordinator)

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**7:30-9:00 AM CONFERENCE REGISTRATION****8:00-8:40 AM OPENING CEREMONY
DRUG INFORMATION ASSOCIATION****8:40-8:45 AM DIA ANNOUNCEMENT****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

Daiichi-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 Biopharmaceutical 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

1:15-2:00 PM LUNCHEON AND ROOM CHANGE

2:00-3:45 PM 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, MHS (Bioethics)

Consultant,
Indian Council of Medical Research, New Delhi, India

3:45-4:00 PM REFRESHMENT BREAK AND ROOM CHANGE

4:00-6:00 PM 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.

Speakers:

Yves Champey, MD

Managing Director, Genzyme India

Sandeep Sahney

Director, Office of Orphan Products Development, Office of Commissioner, FDA, USA

Dr. Agnes Saint-Raymond

Head, Scientific Advice & Orphan Drugs Sector, Pediatric Medicinal Products (SAOD), EMEA, London, UK

Drugs for Neglected Diseases Initiative (DNDi) Project Portfolio

Bhawna Sharma, PhD

Head, DNDi India, New Delhi

6:00 PM CLOSING REMARKS

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

Sites and Investigators in India

Suneela Thatte, MPharm, MBA

Executive Director, Clinical Operations
Quintiles Research India (Pvt.) Ltd., Mumbai

Importance of Strong Study Feasibility Process, Accurate Site Selection and Patient Enrollment Strategies in India

Saurendra Das, MD

Country Head and Director of Operations
Excel Life Sciences

Assuring Quality and Regulatory Compliance of Clinical Trials

Chandrika Arora

Director, Quality Assurance
Quintiles Research India (Pvt.) Ltd., Bangalore

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. Isha Sachdeva Phone:- +911142661122 Fax: +911142662112
 Email: reservations.sheratonnewdelhi@itcwelcomgroup.in.
 Pls cc: owestadmin@itcwelcomgroup.in as well.

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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:

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 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**

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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		Tutorial Fees – Sunday, November 15		Tutorial Fees – Sunday, November 15	
9:00 AM-1:00 PM TUTORIAL WORKSHOP 1	INR 5,000 <input type="checkbox"/>	9:00 AM-1:00 PM TUTORIAL WORKSHOP 1	INR 5,000 <input type="checkbox"/>	9:00 AM-1:00 PM TUTORIAL WORKSHOP 1	INR 5,000 <input type="checkbox"/>
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