DIA’s 3rd Annual Conference on
Drug Discovery and Clinical Development
in India
Scientific, Regulatory, and Social Frontiers

Tutorials: February 28, 2009
Renaissance Mumbai Hotel and Convention Centre, Mumbai, INDIA

This conference will continue to serve as an international and neutral forum to address current solid scientific research in India pertaining to global development of drugs and biologics. Global thought leaders and experts across the pharmaceutical, academia and regulatory agencies will convene to present drug discovery, global clinical research and scientific working groups. Keynote lectures, workshops, and parallel discussion will highlight the conference.

CONFERENCE HIGHLIGHTS
• Regulatory Strategic Discussion with Global Regulatory Leaders
• Opportunities for Establishing Globally Centralized Laboratories in India.
• India’s Patent Laws and their impact on Biopharmaceutical Industry 4 years after Promulgation
• India vs. ICH Regulatory Framework for Safety Reporting
• Bioinformatics and Biometrics

POST-CONFERENCE WORKSHOPS
• Post-marketing Surveillance
• Biostatistics in Drug Development

SESSION TOPICS
• Bioinformatics and Biometrics
• Clinical Trials
• Combination Products
• Drug Delivery
• Drug Discovery
• Regulatory Focus: Development of Anticancer Agents (Drugs & Biologics)
• Development of Biologics
• Pharmacology and Toxicology
• Pharmacovigilance
• Quality by Design
• Current Challenges in Vaccine Development
• Ethics in Clinical Research

FEATURED SPEAKERS
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology, OCF, OTS, CDER, FDA, USA
Supriya Sharma, MD, MPH, FRCP, CCFP
Director General, Therapeutic Products Directorate Health Canada
Vibhakar Shah, PhD
Senior Policy Advisor, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA, USA
Gopalan Narayanan, MD, FRCP, MFPM
Manager/Head, Biologics and Biotechnology, Medicines and Healthcare products Regulatory Agency (MHRA), UK

SCIENTIFIC ADVISORY BOARD COMMITTEE
PUSHPA M. BHARGAVA, PhD
Formerly Director, Center for Cellular and Molecular Biology, India
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Dean and Director General, Institute of Research (India)
NANDINI KUMAR, MD
Consultant, Indian Council of Medical Research, New Delhi, India
NARGES MAHALUXMIVALA, MD
Senior Advisor, Clinical Development Services, Quintiles India
KIRAN MAZUMDAR-SHAW, MD
Chairman and Managing Director, Founder Entrepreneur, Biocon
SHIRLEY MURPHY, MD
former Director, Office of Translational Sciences, CDER, FDA, USA
PREM K. NARANG, PhD
Vice President, Head - Global Regulatory Affairs, Medical Diagnostics, GE Healthcare, USA
SWATI A. PIRAMAL, MBBS, DIM, MPH
Director, Strategic Alliance, Eastern Partner, Nicholas Piramal Indo Limited
SUPRIYA SHARMA, MD, MPH, FRCP, CCFP
Director General, Therapeutic Products Directorate Health Canada
STEPHEN E. WILSON, DrPH, CAPT, USPHS
Director, Division of Biometrics III, CDER, FDA, USA

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!
DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org
WHO SHOULD ATTEND

- Academia
- Biostatistics
- Clinical research and development
- Clinical safety and pharmacovigilance
- Clinical supply operations
- Clinical trial and project management
- Data management
- Drug development and discovery
- Investigator site management
- Medical and scientific affairs
- Outsourcing management/contract research organizations (CROs)
- Pre-clinical development
- Post-graduate students entering pharmaceutical industry
- Procurement and purchasing
- Quality assurance
- Research and development
- Strategic sourcing/planning
- Regulatory affairs
- Government and public policy; lawmakers
- Senior- and executive-level decision makers for clinical trials

Program Development / Tel +1-011-91-22-6741-7625, Cell Phone. 011-9820746323
email Manoj.Trivedi@diaindia.org

CONFERENCE CONTACT INFORMATION

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KEYNOTE SPEAKERS

Surinder Singh, MD  Dr. Surinder Singh was appointed Drugs Controller General of India (DCGI) as of February 2008, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. Prior to his appointment Dr. Singh was Director-in-charge, Regional Drug Testing Lab., (GoI), Chandigarh, in 2007. Dr. Singh served as the Additional Director and Head, Central Drugs Laboratory (GoI), Deputy-Director (QC), National Institute of Biologicals, NOIDA. In addition, Dr. Singh was former Asst. Professor of Microbiology, SP Medical College, Bikaner, and Senior Demonstrator, All India Institute of Medical Sciences (AIIMS). Dr. Singh’s distinguished memberships include the following important government committees and academic institutions:

- Expert member of the committee to establish first BSL-4 Laboratory in India
- Member of the committee to finalize the design and other requirements of National Veterinary Biologicals – Quality Control Centre, Bhopal
- Member of the sub-committee for containment facilities in the Laboratories (BSL-2 and BSL-3) being set up at National Institute of Animal Health, Bhopal
- Member of the committee for “Designing and Setting up of MDR-TB ward, HIV/AIDS ward and BSL3 Laboratory at URS Institute of TB and Respiratory Diseases”
- Member of Recombinant Drug Advisory Panel for evaluation of r-DNA derived therapeutic products
- Member of WHO Expert panel on Vaccines
- Member of Technical Committee of National AIDS Control Organization to draft specifications for equipment and diagnostics for Blood Banks and for identification treatment of STDs
- Expert for inspection of Vaccines and other Biological manufacturing units in India
- Member of committee to create Database on Diagnostics, Vaccines and other Biologicals
- Member of Committee for the Purpose of Control and Supervision of Experiments on Animal (CPCSEA)
- Member of Indian Pharmacopoeia Committee
- Notified Government Analyst for Vaccines and Serums
- Co-chair, Biotech Joint Working Group of US Pharmacopoeia and Indian Pharmacopoeia Commission on Biologics and Biotechnological products
- Vice Chairman of Indian Academy of Vaccinology and Immunology

Habil Khorakiwala  Mr. Khorakiwala is Chairman of the Wockhardt Group, a global, pharmaceutical and biotechnology company headquartered in Hyderabad, India. With 5 research centers and 15 manufacturing plants dotting various countries and continents, Wockhardt’s multicultural, multiethic workforce engages in fulfilling Wockhardt’s vision to become the most admired healthcare group from India.

A keen disciple of “Change Management,” Mr. Khorakiwala has made Wockhardt the first true healthcare group from India. Under his visionary leadership and mentoring, Wockhardt has transformed into India’s leading research-based global healthcare enterprise with relevance in the fields of biotechnology, pharmaceuticals, nutraceuticals, APIs, animal health products and advanced super specialty hospitals.

Mr. Khorakiwala has served as President of the Federation of Indian Chambers of Commerce & Industry (FICCI) in 2007, as well as the National Council Member of the Confederation of Indian Industry (CII). He is past President of Indian Pharmaceutical Alliance, which is the industry association of the top 12 Indian Pharmaceutical companies. Mr. Khorakiwala is also a member of the Board of Governors, Centre for Organisation Development at Hyderabad.

An alumnus of Purdue University and Harvard Business School, Mr. Khorakiwala recently received Purdue University’s “Distinguished Alumnus” distinction for significant contributions to the Profession of Pharmacy.

For his contribution to Indian business and industry, Mr. Khorakiwala has received many prestigious awards, including:

- Entrepreneur of the Year from the UK Trade & Investment
- The Ernst & Young Entrepreneur of the Year Award 2004
- Top CEO 2002 by the Institute of Marketing & Management (IMM), New Delhi
- Lifetime Achievement Awards from the Pharma Excellence Awards 2006 and the International Medical Integration Council
- Shiromani Vikas Award for his “Outstanding and Inspiring Contribution towards National Development”
TUESDAY • FEBRUARY 24

2:00-7:00 PM  CONFERENCE REGISTRATION
LOTUS (FOYER AREA)
Renaissance Mumbai Hotel and
Convention Centre
Near Chinmayanand Ashram,
Powai Mumbai 400 087, India

WEDNESDAY • FEBRUARY 25

7:30-8:30 AM  CONFERENCE REGISTRATION AND
CONTINENTAL BREAKFAST
CONVENTION ENTRANCE/REGISTRATION DESK
Renaissance Mumbai Hotel and
Convention Centre
Near Chinmayanand Ashram,
Powai Mumbai 400 087, India

8:30-8:45 AM  CHAIRPERSON’S OPENING REMARKS
AND WELCOME
Satish C Tripathi, PhD, RAC
Chair, Program Committee and Scientific
Advisory Board, DIA 3rd Annual Conference on
Drug Discovery and Clinical Development in India;
President, Biomedical Consulting International,
Inc., New York, USA
William J. Brassington, MBA
Acting Executive Director
DIA

8:45-9:30 AM  PLENARY KEYNOTE SESSION 1
PHARMACEUTICAL INDUSTRY: TODAY AND TOMORROW
KEYNOTE SPEAKER
Habil Khorakiwala
Chairman, Wockhardt Limited

9:30-10:30 AM  PANEL DISCUSSION
WORLDWIDE REGULATORY LANDSCAPE: CURRENT
REGULATORY INITIATIVES FOR THE DEVELOPMENT OF
DRUGS AND BIOLOGICS IN THE US, CANADA, AND EU
SESSION CHAIRPERSONS
Satish C. Tripathi, PhD, RAC
President, Biomedical Consulting International, Inc.,
New York, USA
Supriya Sharma, MD, MPH, FRCP
Director General, Therapeutic Products Directorate,
Health Canada
Vibhakar Shah, PhD
Senior Policy Advisor, Division of Manufacturing and Product
Quality, Office of Compliance, CDER, FDA, USA
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCP, OTS, CDER, FDA
Gopalan Narayanan, MD, FRCP, MFPM
Manager and Head, Biologicals and Biotechnology, Medicines
and Healthcare products Regulatory Agency (MHRA), UK

10:30-11:00 AM  REFRESHMENT BREAK

11:00 AM-12:30 PM  PANEL SESSION 3
WORLDWIDE REGULATORY LANDSCAPE: CURRENT
REGULATORY INITIATIVES FOR THE DEVELOPMENT OF DRUGS
AND BIOLOGICS IN THE US, CANADA, AND EU

12:30-1:45 PM  LUNCHEON AND NETWORKING
OPPORTUNITY

1:45-2:15 PM  SESSION 4
EXPLORATORY INVESTIGATIONAL NEW DRUG APPLICATIONS
Mohinder S. Bathala, PhD
Senior Director, Bioanalysis and Metabolism
Daiichi Sankyo

2:15-4:15 PM  SESSION 5
REGULATORY FOCUS: DEVELOPMENT OF ANTICANCER
AGENTS (DRUGS & BIOLOGICS)
SESSION CHAIRPERSONS
P.K. Narang, PhD, FCP
Vice President, Head – Global Regulatory Affairs, Medical
Diagnostics, GE Healthcare
Vinod Raina, MD
Professor and Head of Medical Oncology
Institute Rotary Cancer Hospital
All India Institute of Medical Sciences

Cancer remains one of the leading causes of mortality. Research and drug
development efforts continue to focus on both biologics and chemically
synthesized small molecules with potential to improve treatment out-
comes. Significant global investments made by pharmaceutical/biotech
industry are trying to leverage evolving science to expedite efforts to
register new drugs. Though small molecule development has been and
continues to be the mainstay, there is a growing interest in development of
biologics. Biologic products are generally derived through the metabolic
activity of living organisms. Therefore, they tend to be more variable and
structurally complex than small synthesized molecules, as their manufac-

3
This session will provide strategic framework for health authority oversight & expectations critical to achieving scientific – regulatory rigor for an effective development and registration of biologic therapeutics for treatment of cancer (while noting important differences from drug – small molecules). Presenters will focus on relevant regulatory guidance and considerations for pre-clinical and clinical development effort for oncology biologics.

**INTRODUCTION**
P.K. Narang, PhD, FCP  
Vice President, Head – Global Regulatory Affairs, Medical Diagnostics, GE Healthcare

**REGULATORY ISSUES AND PERSPECTIVES: BIOLOGICS FOR CANCER TREATMENT**  
**US-FDA**  
Raj K. Puri, MD, PhD  
Director, Division of Cellular and Gene Therapies  
CBER, FDA

**CHALLENGES AND CONSIDERATIONS IN DEVELOPMENT OF BILOGIC CANCER THERAPEUTICS**  
**PRECLINICAL**  
Andrew McDougal, PhD  
Toxicologist, Office of Food Additive Safety  
DABT, CDER, FDA

**CLINICAL**  
Kaushik Shastri, MD  
Medical Reviewer  
Division of Biologic Oncology Products, Office of Oncology Products, CDER, FDA

**PANEL DISCUSSION AND Q&A SESSION**  
All presenters

4:15-5:00 PM  **SESSION 6: KEYNOTE SPEAKER**  
Surinder Singh, MD (Invited)  
Drug Controller General of India (DCGI), India

5:00-5:30 PM  **SESSION 7**  
**OPPORTUNITIES FOR ESTABLISHING GLOBALLY CENTRALIZED LABORATORIES IN INDIA**  
Palat K. Menon MD, PhD  
Medical Director  
Quest Diagnostics India Pvt Ltd

5:30-7:30 PM  **NETWORKING RECEPTION**  

7:30-8:30 AM  **REGISTRATION AND CONTINENTAL BREAKFAST**

8:30-8:35 AM  **OPENING REMARKS**  
Professor Suresh K. Gupta, PhD, DSc  
Dean and Director General  
Institute of Clinical Research (India)

8:35-9:15 AM  **LECTURE**  
Overview of GCP and Bioresearch Monitoring  
Mathew T. Thomas, MD  
Health Science Administrator, Office of Orphan Products Development, Office of Compliance, OSHC, FDA

9:15-10:30 AM  **SPECIAL PLENARY AND PANEL DISCUSSION**  
FDA: Beyond the Borders Initiative  
Beverly Corey, DVM  
Acting Country Director, India  
FDA  
Albinus D’Sa, PhD  
Deputy Country Director, India  
FDA

10:30-11:00 AM  **SESSION 8**  
Drug Development for Rare and Neglected Diseases: Economic, Clinical and Regulatory Considerations  
Session Chairperson  
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 and will describe the current challenges associated with innovation in this area for both Indian and non-Indian pharmaceutical companies and related service providers. In addition, it will address current initiatives in global health and share views on how India can contribute to global needs in neglected diseases.

**FDA INCENTIVES FOR PRODUCT DEVELOPMENT FOR RARE DISEASES**  
Mathew T. Thomas, MD  
Health Science Administrator, Office of Orphan Products Development, Office of Compliance, OSHC, FDA

11:00-11:30 AM  **REFRESHMENT BREAK**
CONCURRENT SESSION 10A  
**ABCS OF BIOLOGICS – GLOBAL PERSPECTIVES**  
**Session Chairperson**  
Gopalan Narayanan, MD, FRCP, MFPM  
Manager and Head, Biologicals and Biotechnology, Medicines and Healthcare products Regulatory Agency (MHRA), UK  

Biototechnology derived medicinal products include a variety of products, ranging from a simple peptide through monoclonal antibodies to advanced therapies such as gene therapy and cell therapy. Because these products are derived from a living system, they pose certain unique challenges. In practice, there are some areas that need particular attention at this point in time.  

- Comparability of a product through its various stages of evolution is a significant issue that affects almost all products. This could delay approval significantly.  
- Biosimilar products: These are the biological equivalent of small molecule chemical generics. A pathway has been established in Europe. Many regional/national agencies as well WHO is actively trying to establish regulatory/scientific procedures for such products.  
- Advanced Therapies: These generally include gene therapy, cell therapy and tissue engineering. Although these are still evolving, they promise exciting possibilities while posing some special (potential) problems.  

**Complexities of Biologicals**  
Gopalan Narayanan, MD, FRCP, MFPM  
Manager and Head, Biologicals and Biotechnology, Medicines and Healthcare products Regulatory Agency (MHRA), UK  

**Biosimilars: Where Next?**  
Dr. Cecil Nick  
Vice President (Technical), PAREXEL Consulting, UK  

**Legislative and Policy Developments for Advance Therapy Medicinal Products – A Global Overview**  
Dr. Lincoln Tsang  
Arnold and Porter (UK) LLP, UK, Formerly Head of Biologicals, MHRA  

**Immunogenicity of Biosimilars**  
Deven Parmar, MD  
Vice President, Clinical Research, Wockhardt Limited  

**Panel Discussion**  
Raj K. Puri, MD, PhD (Invited)  
Director, Division of Cellular and Gene Therapies, CBER, FDA  

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**CONCURRENT SESSION 10B**  
**Impact of QT Interval Prolongation on Drug Development**  
**Session Chairpersons**  
Deepti Sanghavi, BHMS, PGDCR  
Associate QECG Project Manager  
Quintiles ECG Services  
Snehal Kothari, MD, DM, FACC  
Medical Director, Quintiles ECG Services, India  

It has been seen time and again that many drugs have an undesirable property to delay cardiac repolarisation i.e. they cause marked prolongation of QT interval which eventually leads to ventricular arrhythmia particularly Torsades. Prolongation of the QT interval by noncardiac drugs is the commonest cause of drug delays in development, nonapprovals and withdrawal after marketing. Hence, we need to continuously monitor QT interval as a part of safety assessment of new drugs. This has culminated into a new regulatory guidance ICH E14 document which advocates a definitive or Thorough QT Phase I trial irrespective of preclinical cardiac findings to assess the potential of a drug to prolong QT interval. The guidance also recommends the intervals be measured by few skilled readers from ECG core laboratory. In this session, we will discuss the impact of QT interval in Clinical Trials – Inclusion and Exclusion, Patient Safety and design, conduct and analysis of Thorough QT studies.  

**Introduction to QT Interval Prolongation**  
Chris Pollard, PhD  
Senior Principal Scientist  
AstraZeneca, UK  

**ICH E14 Recommendations on QT Interval**  
Snehal Kothari, MD, DM, FACC  
Medical Director  
Quintiles ECG Services, India  

**Statistical Analysis of Thorough QT Studies**  
K. V. Palanichamy, PhD  
Project Manager-Biostatistics  
Tata Consultancy Services  

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4:00-4:15 PM **COFFEE BREAK**
FRIDAY • FEBRUARY 27

7:00-8:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:05 AM  OPENING REMARKS
Fernando Quezada, MPA
Executive Director, Biotechnology Center of Excellence Corporation, USA

8:05-9:35 AM  SESSION 12
PEDIATRIC GLOBAL DRUG DEVELOPMENT – REGULATIONS, INCENTIVES, AND IMPROVED CARE
SESSION CHAIRPERSON
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCP, OTS, CDER, FDA

FDA PERSPECTIVE
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology
OCP, OTS, CDER, FDA

REGULATORY AND OPERATIONAL PERSPECTIVES IN RUNNING A PEDIATRIC STUDY IN INDIA
Syed Mubarak Naqvi, MD
Vice President, Operations
Clini Rx Research Pvt. Ltd.

9:35-10:05 AM  CONCURRENT SESSION 11B
CLINICAL DATA MANAGEMENT AND BIOSTATISTICS
SESSION CHAIRPERSON
Munish Mehra, PhD
Managing Director
Global Drug Development Experts

ICH E9 AND STATISTICAL PRINCIPLES FOR CLINICAL TRIALS
Munish Mehra, PhD
Managing Director
Global Drug Development Experts

BIOMARKERS AND SURROGATE ENDPOINTS IN DRUG DEVELOPMENT
Speaker Invited

EVOLVING CONCEPTS IN “ADAPTIVE TRIAL DESIGN AND NON-INFERIORITY HYPOTHESIS TESTING”
Stephen E. Wilson, DrPH, CAPT. USPHS (Invited)
Director, Division of Biometrics III, CDER, FDA, USA

CLINICAL DATA MANAGEMENT IN 2010 AND BEYOND: INDIA AS A LEADER
Nimita Limaye, PhD
Vice President (CDM and Medical Writing)
SIRO Clinpharm Pvt Ltd

MULTIPLE REGULATORY AGENCIES COMPLIANT CLINICAL DATA PREPARATION – PRACTICAL CHALLENGES FACED IN GLOBAL ENVIRONMENT
Kalyan Gopalakrishnan
Executive Vice President
TAKE Solutions, Inc, Princeton, NJ

6:30 PM  END OF DAY 2
Contemporary clinical trials are impacted by cultural, political, economic and societal factors. In the current era of globalization when the sponsor of a clinical trial and the sites of that trial are in different geographies, these factors, being dissimilar from country to country, have the potential to cause differences in ethical understanding and interpretation. Cross cultural and cross country sensitivity to this aspect are therefore of extreme importance in global clinical trials and global conferences like the DIA allow relevant discussion between people of different geographies.

The number and complexity of clinical trials being conducted in India by overseas sponsors are increasing. There is also an increased awareness of human subject protection in the stakeholders of the clinical trials and in the general public in India.

Research ethics has become an important topic for discussion at all clinical research forums. The session serves as an opportunity for experts to put forward their views on ethical aspects of clinical research to the knowledgeable and interested participants who form DIA meeting attendees. The topics discussed will be varied from the ethics of clinical trials in vulnerable subjects through the responsibilities of the contemporary ethics committee. There will be opportunities for exchange of viewpoints and comments.

**Panelists**

**The Investigator**
Dr. Vikas Mohan Sharma  
Associate Director, Medical & Scientific Services  
Quintiles Research (India) Pvt. Ltd.

**The Ethics Committee**
Sangeeta Desai, MD, DTM  
Professor of Pathology  
Tata Memorial Cancer Hospital & Research Centre, Mumbai, India

**The Media**
Gauri Kamath  
Assistant Editor  
Business World, Mumbai, India

**The Citizenry**
Vandana Gupta  
Founder  
V-CARE Foundation, Mumbai, India

**Ethical Issues In Non-Therapeutic Trials**

**Session Chairperson**
Narges Mahaluxmivala, MD  
Senior Advisor, Clinical Development Services  
Quintiles Research (India) Pvt. Ltd.

- **Recruitment of Participants**  
  Dr. Arun Bhatt  
  President, Clininvent Research Pvt. Ltd.

- **Compensation for Participants and for Trial-related Injury**  
  Urmila Thatte, MD, DNB, PhD, FAMS  
  Professor and Head, Department of Clinical Pharmacology  
  Seth GS Medical College and KEM Hospital, Mumbai

- **Ethical Review Focusing on Risk-benefit Assessment**  
  Dr. Sripada Venkata Joga Rao  
  LEGALEXCEL, Bangalore, India

- **Phase 0 Trials**  
  Kiran Marthak, MD  
  Director, Veeda Clinical Research, Mumbai, India

**Current Challenges in Vaccine Development**

**Session Chairperson**
Ruchika Raval, MS, RAC  
President, Global Pharmaceutical Regulations, USA and Bangalore, India

The Vaccine development is perhaps one of the most arduous amongst all therapeutic products. The recent E&Y report suggests that it takes US$1.2B and 9-12 years to develop a single therapeutic vaccine. In the last decade, FDA has declined the request to approve adjuvant as a stand alone therapy and has approved only 2 vaccines. While EMEA has approved one new adjuvant and a couple of vaccines, the approval rate is still less than optimistic. What are the significant challenges that make this particular therapeutic area a challenge for the innovator? Are their issues with access to funding and access of vaccine procurement? How is this area the most funded in terms of public health protection in US and EU? Our combined panel of speakers will provide insight on these vaccine challenges.

**Overview of Global Vaccine Landscape and Session Scope**
Ruchika Raval  
Session Chair and President, Global Biopharm Regulations

**Aseptic Processing Challenges for a Typical Vaccine – A GMP Perspective**
M.S. Mahadevan  
Bioprocess Division, Millipore India Pvt. Ltd., Bangalore, India

**Product Development of Rota Virus Vaccine 116B for Treatment of Children’s Diarrhea**
Rayasam (Ray) S. Prasad  
Chief Operating Officer  
Global (Biologics), Biological E. Limited, India
CLINICAL DEVELOPMENT OF MENINGOCOCCAL A CONJUGATE VACCINE FOR EPIDEMIC MENINGITIS IN SUB-SAHARAN AFRICA
Prasad S. Kulkarni, MD
Medical Director, Serum Institute of India Ltd

ACCESS TO VACCINES: INDUSTRY INCENTIVES, GOVERNMENT INDUCTION
Cyrus Chowdhury, MS
Consultant, Insight Strategy

5:30-5:45 PM CLOSING REMARKS AND ANNOUNCEMENT FOR FALL 2009 CONFERENCE

5:45 PM CONFERENCE ADJOURNED

SATURDAY • FEBRUARY 28

8:00-9:00 AM POST-CONFERENCE TUTORIAL REGISTRATION AND CONTINENTAL BREAKFAST
LOTUS (FOYER AREA)
Renaissance Mumbai Hotel and Convention Centre
Near Chimbayanand Ashram, Powai Mumbai 400 087, India

9:00 AM-12:30 PM POST-CONFERENCE TUTORIAL 1
Continuing education credits are not offered for these tutorials.

POSTMARKETING SURVEILLANCE
POST-CONFERENCE TUTORIAL LOCATION
Lotus Room

9:00-10:00 AM TUTORIAL INSTRUCTOR
Solomon Iyasu, MD, MPH
Director, Division of Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

10:00-10:30 AM REFRESHMENT BREAK

10:30-11:00 AM TUTORIAL COORDINATOR AND INSTRUCTOR
Sciformix Representative Invited

11:30-12:30 PM TUTORIAL INSTRUCTOR
Darshan Bhatt, MBBS, DipAvMed, MD, MPhil
Consultant in Pharmacovigilance, Clinical Research and Aerospace Medicine

12:30-1:30 PM NETWORKING LUNCHEON

1:30-5:00 PM POST-CONFERENCE TUTORIAL 2
INTRODUCTION TO DESIGN, CONDUCT AND REVIEW OF CLINICAL TRIALS IN US DRUG DEVELOPMENT – STATISTICAL PRINCIPLES AND GOOD CLINICAL PRACTICES
POST-CONFERENCE TUTORIAL LOCATION
Lotus Room

1:30-3:00 PM TUTORIAL INSTRUCTORS
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III
CDER, FDA, USA
Munish Mehra, PhD
Managing Director
Global Drug Development Experts

Part I Topics:
• A Quick Overview of Drug Development and Phases of Clinical Trials
• Basic Tenets of Good Clinical Practices and the role of Statistics
• Variables Measured (Baseline Characteristics, Efficacy, Safety)
• Basic Principles in Avoiding Bias (Randomization and Blinding)
• Commonly Used Designs (Parallel and Cross Over)

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM Part II Topics:
• Issues to Consider in Designing Trials, Writing Protocols, Developing
• CRFs and Configuring Data Collection Systems
• Issues to Consider during Trial Conduct
• Analysis and Reporting
• ISS and ISEs
• Current frontiers in Statistical Principles – Adaptive Trials, Non-inferiority designs etc.

5:00 PM TUTORIALS ADJOURNED

Dont’ Miss the DIA 2nd Indian Annual Regulatory Conference
Access to Medicines: Regulatory and Public Health Interface
Tutorials: May 3, 2009
Conference: May 4-5, 2009
Hyatt Regency Hotel, Mumbai, INDIA
To register, visit www.diahome.org
Please contact the Renaissance Mumbai Hotel and Convention Centre by telephone at +91-22-6692-8888

FAX OR EMAIL TO THE ATTENTION OF: Mr. Chandrashekhar Joshi, Associate Director of Sales
PHONE NO.: +91-22-6692-8888
FAX NO.: +91-22-6692-7077
EMAIL TO: rhi.bombr.asst.sales.mgr1@renaissancehotels.com

Personal Details (To enable you to be pre-checked into the room)

Name _____________________________________________________________ Designation ______________________________________________
Organization __________________________________________________________________________________________________________
Address ________________________________________________________________________________________________________________
City _____________________________ State/Province ______________ Zip/Postal Code ________________ Country __________________________
Telephone _____________________________________________________ Fax __________________________________________________________
email _______________________________________________________________________________________________________________________
(email address required for receipt of reservation confirmation.)
Passport Number ______________________________________________ Nationality ____________________________________________________
Date of Issue ___________________________ Place of Issue ________________________________________ Date of Birth __________________

Flight and Arrival Details

Arrival date _______________________ Arrival time __________________ Flight No: _______________ From: _________________________
Departure date ____________________ Departure time _______________ Flight No: _______________ To: _________________________________
Room category _______________________________ Sgl/Dbl room ____________________________ Airport pick-up required (YES/NO) ________

Room Rates Applicable at the Renaissance Mumbai Hotel and Convention Centre, Mumbai

<table>
<thead>
<tr>
<th>Category of Rooms</th>
<th>SINGLE*</th>
<th>DOUBLE*</th>
<th>Choice of Room Required</th>
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<tr>
<td></td>
<td>INR 13,000</td>
<td>INR 13,500</td>
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*For foreign delegates, rates will be as per the dollar value on the date of departure.
*All Government taxes and duties would be charged extra as and when applicable. Please note that taxes are subject to change as per change in
government norms.

The above rates are on a per-night basis, and include accommodation in well-appointed rooms and a continental breakfast at the
Lake View Café.

1. A block booking has been made for this conference with a limited number of rooms in each of the above categories. Rooms will be
reserved as per availability at the time of receipt of this reservation request.
2. One way airport transfers to domestic airport will be charged at INR 1400/- +taxes and 2 way at INR 2800/- +taxes. For international airport the charges are
INR 1200/- +taxes and 2 way at INR 2400/- + taxes,
3. The group check-in time is 1500 hr and check-out time is 12:00 noon. Early check-in/late check-out will only be given subject to availability.
4. If a cancellation is received less than 2 days before the date of check in, there would be a retention charge of 50% to the credit card for
one night.
5. All room and incidental charges are chargeable to your personal account and must be settled upon check-out.
6. ROOMS WILL BE CONFIRMED ONLY AGAINST A GUARANTEE OF AN APPROVED CREDIT CARD.

Credit Card No.: ___________________________ MASTERCARD / VISA / AMEX ____________
Name of Card Holder ___________________________ Expiration Date ______________________
Date of Booking ________________________________
Guest Signature ___________________________________________

DO NOT FAX HOTEL RESERVATION FORMS TO DIA.
TRAVEL AND HOTEL  The most convenient airport is Chattrapathi Shivaji International Airport and attendees should make airline reservations as early as possible to ensure availability. The hotel is 5 km from the international and 9 km from the domestic airport. The Renaissance Mumbai Hotel and Convention Centre is holding a block of rooms at the reduced rate until January 23, 2009, for the meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Please contact the Renaissance Mumbai Hotel and Convention Centre by telephone at +91-22-6692-8888 and mention the DIA meeting, or use the attached room reservation form on page 4. The hotel is located at #2 & 3B Near Chinmayanand Ashram, Powai, Mumbai 400 087, India.

- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

CANCELLATION POLICY: On or before FEBRUARY 11, 2009

Cancellations must be in writing and received by February 11, 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:

- Standard = INR 3,000 • Academy/Government = INR 2,000 • Tutorial = INR 1,000 • Student = INR 1,000

Please check the applicable category:

- ☐ Academia ☐ Government ☐ Industry ☐ CRO ☐ Student

To take advantage of all the benefits of DIA membership, visit www.diahome.org and click on Membership.


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

Full Meeting Cancellation (All refunds will be issued in the currency of original payment):

- Standard = INR 3,000 • Academy/Government = INR 2,000 • Tutorial = INR 1,000 • Student = INR 1,000

CREDITS

- Tutorial = INR 5,270
- Post Marketing Surveillance = INR 5,270

Please enter all credit card information requested below, and FAX TO DIA in the USA at +1-215-442-6199.

- ☐ Visa ☐ MC Exp. Date ______________________

Please check payment and submission method below.

- ☐ DEMAND DRAFT/CHEQUE

Completed form, along with draft/cheque made payable to DIA (India) Private Limited, should be sent to: Leena Amanna, Operations Manager, DIA (India) Private Limited, No. 6, Behind Mittal Industrial Estate, Gayatri Commercial Complex, Andheri Kurla Road, Andheri-east, Mumbai 400059 India, Phone: +91-22-6765-3227

Email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT’S BUSINESS CARD.