DIA's 3rd Annual Conference on

Drug Discovery and Clinical Development in India

Scientific, Regulatory, and Social Frontiers

DIA Drug Information Association

Conference: February 25-27, 2009
Tutorials: February 28, 2009

Renaissance Mumbai Hotel and Convention Centre, Mumbai, INDIA

KEYNOTE SPEAKERS

SURINDER SINGH, MD
Drug Controller General of India (DCGI)

HABIL KHORAKIWALA
Chairman
Wockhardt Limited

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

CHAIR FOR SCIENTIFIC ADVISORY BOARD AND PROGRAM COMMITTEE

SATISH C. TRIPATHI, PhD, RAC
President, Biomedical Consulting International, Inc., New York, USA

PROGRAM COMMITTEE

KIRAN MARTHAK, MD
Director, Veeda Clinical Research (P) 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

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Vice President, Clinical Research, Wockhardt Limited

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Professor and Head of Medical Oncology, Institute Rotary Cancer Hospital
All India Institute of Medical Sciences

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President, Global Pharmaceutical Regulations, USA and Bangalore, India

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Senior Policy Advisor, Division of Manufacturing and Product Quality
Office of Compliance, CDER, FDA, USA

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Associate QECG Project Manager, Quintiles ECG Services, India

SCIENTIFIC ADVISORY BOARD COMMITTEE

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Formerly Director, Center for Cellular and Molecular Biology, India

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

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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 Alliances and Communications, Nicholas Piramal India Limited

SUPRIYA SHARMA, MD, MPH, FRCPC
Director General, Therapeutic Products Directorate, HealthCanada

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

Featured Speakers

Regulatory

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

Supriya Sharma, MD, MPH, FRCPC
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

Narges Mahaluxmivala, MD
Senior Advisor, Clinical Development Services, Quintiles India

Social Frontiers

Mathew T. Thomas, MD
Health Science Administrator, Office of Orphan Products Development, Office of Compliance, OSHC, FDA

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

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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

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PROGRAM DEVELOPER

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CONFERENCE CONTACT INFORMATION

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email Leena.Amanna@diaindia.org

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 Nationall Veterinary Biologicals – Quality Control Centre, Bhagpat
- 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, Bagpat
- Member of the committee for "Designing and Setting up of MDR-TB ward, HIV/AIDS ward and BSL3 Laboratory at LRS 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 Sera
- 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 headquarteresd in Hyderabad, India. With 5 research centers and 15 manufacturing plants dotting various countries and continents, Wockhardt's multicultural, multiethnic 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 speciality 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:

- Entreprenuer 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 SESSION 2**

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, FRCPC
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

Solomon Iyasu, MD, MPH
Director, Division of Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

Raj K. Puri, MD, PhD
Director, Division of Cellular and Gene Therapies
CBER, FDA

Mathew T. Thomas, MD
Health Science Administrator, Office of Orphan Products Development, Office of Science and Health Coordination, Office of the Commissioner, FDA

Andrew McDougal, PhD
Toxicologist, Office of Food Additive Safety
DABT, CDER, FDA

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

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 outcomes. 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 manufacture involves use of animals and/or microorganisms. Unlike small molecules, for which there is a significant body of experience in academics, industry and regulators, development of biologics poses unique challenges.

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 Biologic 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**

THURSDAY • FEBRUARY 26

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**

11:30 AM-1:15 PM **SESSION 9**

Clinical Trials in India: Regulatory and Legal Perspectives

Session Chairperson

Dr. Chandrashekhar N. Potkar
Head, Clinical Trials
Pfizer India

Presenters

Shantanu Basu, PhD, JD
Of Counsel-Intellectual Propoerty
Mintz, Levin, Cohn, Ferris, Glorsky and Popeo Intellectual Property, LLP

Dr. Chandrashekhar N. Potkar
Head, Clinical Trials
Pfizer India

1:00-2:00 PM **NETWORKING AND LUNCHEON OPPORTUNITY**

2:00-4:00 PM **CONCURRENT SESSIONS 10**

Concurrent Session A Grand Ballroom 1

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

Biotechnology 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

Concurrent Session B Grand Ballroom 2

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 ICHE14 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

4:00-4:15 PM **COFFEE BREAK**

4:15-6:30 PM **CONCURRENT SESSIONS 11**

CONCURRENT SESSION 11A

Issues in Pharmacovigilance: Selected Topics

Session Chairperson

Solomon Iyasu, MD, MPH
Director, Division of Epidemiology
Office of Surveillance and Epidemiology, CDER, FDA

Pharmacovigilance Inspection Readiness
Moin Don
Associate Director (Asia Pacific), Pharmacovigilance Quality Assurance, Johnson & Johnson PRD

Optimizing Data Collection and Review for Efficient Signal Detection in Clinical Development
Deepa Arora, MD
Medical Advisor- International Clinical Research
Wockhardt Limited, Wockhardt Towers

Phamacovigilance – Beyond Regulatory Compliance
Professor Santanu K. Tripathi, MD, DM
Head of Pharmacology, Burdwan Medical College, Burdwan, India

Is Data-mining Approach Sufficient for Signal Detection in Pharmacovigilance?
Darshan Bhatt, MBBS, DipAvMed, MD, MPhil
Consultant in Pharmacovigilance, Clinical Research and Aerospace Medicine

Overview of Pharmacovigilance Matrix and Operations Oversight
Imran Ali, MPharm, MBA
Associate Director
Pharmacovigilance Center Quintiles
Pharmacovigilance Center, Bangalore, India

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**

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 **SESSION 13**

Implementation of India Operations: Achieving Operational and Business Success

Mahesh Singh, MS, MBA
Partner Life Sciences, PRTM Consultants

10:05-11:05 AM **PANEL SESSION 14**

Quality of Medicinal Products

Session Chairperson

Vibhakar Shah, PhD
Senior Policy Advisor, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA, USA

Quality by design, i.e., quality cannot be tested into products; it should be built-in or should be by design, is rarely a new concept in industrial sectors other than pharmaceutical. But lately in last five years, with the launch of (i) sweeping regulatory initiatives such as Critical path Initiative for New Medical Products, Pharmaceutical CGMPs for the 21st Century: A Risk-based Approach, and Process Analytical Technology by the US Food and drug Administration, and (ii) ICH Quality Guidelines (Q8, Q9, Q10), this picture has gradually started to change. This session will focus on the current status and future of these initiatives and guidelines with respect to their implementation in the drug development, manufacture, quality control and quality assurance through the product life cycle.

Mansoor Khan, PhD
Director, Division of Product Quality Research
OTR, OPS, CDER, FDA

T. G. Venkateshwaran, PhD
Senior Director, New Product Quality Operations
Global Quality and Compliance, Wyeth Pharmaceuticals

11:05-11:15 AM **COFFEE BREAK**

11:15AM-12:30 PM **SESSION 15**

Panel Discussion on 'Ethical Issues in Clinical Trials in Individuals with Reduced Autonomy'

Moderators

Urmila Thatte, MD, DNB, PhD, FAMS
Professor and Head, Department of Clinical Pharmacology
Seth GS Medical College and KEM Hospital, Mumbai

Nandini Kumar, MD
Consultant, Division of Basic Medical Sciences, Indian Council of Medical Research, Ansari Nagar, New Delhi, India

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

12:30-1:15 PM **LUNCHEON AND NETWORKING OPPORTUNITY**

1:15-3:00 PM **SESSION 16**

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

3:00-3:30 PM **REFRESHMENT BREAK**

3:30-5:30 PM **SESSION 17**

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
Facilitator
M.S. Mahadevan
Bioprocess Division, Millipore India Pvt. Ltd., Bangalore, India

Product Development of Rota Virus Vaccine 116B for Treatment of Children's Diarrhea
Facilitator
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 Chinmayanand 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

ROOM RESERVATION FORM

3rd Annual Conference on Drug Discovery and Clinical Development in India

February 25-28, 2009 – Renaissance Mumbai Hotel and Convention Centre, Mumbai, INDIA

We request you to fax this Hotel Reservation Form, indicating your preference, latest by Friday, January 23, 2009, as bookings will be subject to availability. Reservations will have to be guaranteed against a credit card.

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

Category of Rooms	SINGLE*	DOUBLE*	Choice of Room Required
	INR	INR	
*Standard	13,000	13,500	

***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.**

MEETING CONTACT INFORMATION

India Contacts: Ms. Leena Amanna, Operations Manager, DIA (India) Private Limited; Phone: +91-22-6765-3227; Fax: +91-22-2859-4543; Email: Leena.Amanna@diaindia.org; or **Manoj Trivedi, Manager, Marketing and Program Development. DIA (India) Private Limited;** Phone: +91-22-6741-7625; Email: Manoj.Trivedi@diaindia.org.

EXHIBIT CONTACT INFORMATION: Attendees may visit the exhibits during the meeting and receptions. **For exhibitor information or to receive an exhibit application,** please contact **Manoj Trivedi, Manager, Marketing and Program Development. DIA (India) Private Limited;** Phone: +91-22-6741-7625; Email: Manoj.Trivedi@diaindia.org. or **Jeff Korn, Exhibits Associate, DIA Worldwide Headquarters;** Phone +1-215-442-6184; Email: Jeff.Korn@diahome.org

CANCELLATION POLICY: On or before FEBRUARY 11, 2009

Cancellations must be in writing and be 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:

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 1,000**

PLEASE CONSIDER THIS FORM AN INVOICE

3rd Annual Conference on Drug Discovery and Clinical Development in India

Meeting I.D. # 08953 – February 25-28, 2009 – Renaissance Mumbai Hotel and Convention Centre, Mumbai, INDIA

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

Registration Fees – Wednesday, February 25 – Friday, February 27, 2009

Register online at www.diahome.org or check payment and submission method below.

Be a DIA Member	INR 1,600 ❑
▶ Standard Member	INR 14,600 ❑
Total	INR 16,200 ❑
▶ Standard Nonmember	INR 16,500 ❑
▶ Academia/Government	INR 10,500 ❑
▶ Student*	INR 5,000 ❑

A limited number of student registrations are available.

A student is an undergraduate/graduate who can document enrollment in an accredited, degree granting, academic program. Student registration is by fax or mail ONLY. Please send completed registration form, copy of student identification, and payment.

▶ **Tutorial Fees – Saturday, February 28**

9:00 AM-12:30 PM	#1 Post Marketing Surveillance	INR 5,270 ❑
1:30-5:00 PM	#2 Biostatistics in Drug Development	INR 5,270 ❑

❑ **CREDIT CARD**

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

☐ Visa ☐ MC *Exp Date* _____

_____
Card #

_____
Name (printed)

_____
Signature

❑ **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

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

Please check the applicable category: ❑ Academia ❑ Government ❑ Industry ❑ CRO ❑ Student

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name (Family Name) First Name M.I. Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title Affiliation (Company)

Address (Please write your address in the format required for delivery to your country.)

City State Zip Country

Telephone Number Fax Number

email (Required for confirmation)

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