

Pre-market Evaluation of Quality and Bioavailability



February 2-3, 2009, Scitech Center, Mumbai

February 5-6, 2009, Taj Banjara, Hyderabad

PROGRAM CHAIR

Sultan Ghani

Director DIA India

Dr. Nandkumar Chodankar

Chair

PACI - India

SPEAKERS

Vilayat A. Sayeed, PhD

Director, Division of Chemistry III FDA/CDER/OPS/OGD

Dr. Stephanie Parra

Manager of Generic Drugs: Quality Division Bureau of Pharmaceutical Sciences TPD Health Canada

Dr. Jan Welink

Senior Pharmacokineticist Dutch Evaluation Board, The Netherlands

Shereeni Veerasingham, MBBS, PhD

Assessment Officer
Division of Biopharmaceutics Evaluation 2
Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate

Join Representatives from the US FDA, EU, and Health Canada to Discuss the Pre-market Evaluation of Quality and Bioavailability Requirements

This workshop will clarify the approval requirements for drugs developed in India for global markets. You will have the opportunity to participate in the exchange of alternative perspectives from industry, academia, and regulatory professionals.

FEATURED TOPICS

- Current regulatory requirements for pre-market applications
- Current challenges facing quality and bioavailability
- Deficiencies in drug applications from Indian manufacturers

WHO SHOULD ATTEND

This program will benefit individuals involved in:

- Regulatory affairs
- Research and development
- Quality control
- Quality assurance
- Regulatory assessment
- Outsourcing management/Contract Research Organizations (CRO)
- ► Good Clinical Practices (GCP)
- ► Chemical Manufacturing & Controls (CMC)
- Product selection

CONTACT INFORMATION

Conference: Leena Amanna, Phone +91-22-67653226, Fax +91-22-28594543 email: Leena.Amanna@diaindia.org

TRAVEL AND HOTEL The most convenient airports are Chattrapathi Shivaji International/Domestic Airport Mumbai and Shamshabad Airport Hyderabad and attendees should make airline reservations as early as possible to ensure availability.

▶ 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

Sultan Ghani, Director, DIA (India) Private Limited; Phone: +91-22-6765-3228; Email: Sultan.Ghani@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 **Ms. Leena Amanna, Operations Manager, DIA (India) Private Limited;** Phone: +91-22-6765-3227; Fax: +91-22-2859-4543; Email: Leena.Amanna@diaindia.org

CANCELLATION POLICY: On or before JANUARY 20, 2009

Cancellations must be in writing and be received by January 20, 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

PLEASE CONSIDER THIS FORM AN INVOICE

1st Workshop on Pre-market Evaluation on Quality and Bioavailability☐ Meeting I.D. # 09950 − February 2-3, 2009 − Scitech Center, Mumbai, INDIA ☐ Meeting I.D. # 09951 − February 5-6, 2009 − Taj Banjara, Hyderabad, INDIA

You must indicate which workshop you will be attending, by checking a box above.

Registration Fees Registration fee includes refreshing luncheons and will be accepted by mail, fax, or online.	nent breaks an	ıd	Register online at www.diahome.org or check payment and submission method below.	
Be a DIA Member Standard Member Rate Total	INR 1,600 INR 8,400 INR 10,000		□ 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	
Standard Nonmember	INR 10,000			
Academia/Government	INR 6,000			
Student* *A limited number of student registrations are available. A student is an undergraduate/graduate who can document enrolln accredited, degree granting, academic program. Student registration Please send completed registration form, copy of student identification.	n is by fax or mai		Name (printed) Signature	
WENUE MUMBAI – Meeting I.D. #09950 Scitech Center, 7, Prabhat Center, Joegeshwari (W), Mumbai 400 102. HYDERABAD – Meeting I.D. #09951 Hotel Taj Banjara, Banjara Hills, Hyderabad.			□ 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				
ast Name (Family Name)	First Name		M.I. Degrees Dr. Mr. Ms.	
ob Title Affiliation (Company)				
Address (Please write your address in the format required for delivery to your cou	untry.)			
City Stat	e		Zip Country	
elephone Number			Fax Number	

email (Required for confirmation)