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Clinical Research and Product Registration of Biopharmaceuticals/ Vaccines in India and China

DRUG INFORMATION ASSOCIATION

April 26-27, 2007 | Omni San Diego Hotel, San Diego, CA, USA

PROGRAM CHAIRPERSON

ROMI SINGH, PHD
Executive Director
Global Regulatory Affairs
Amgen, Inc.

PROGRAM COMMITTEE

MARK ENGEL
Chairman
Excel PharmaStudies, China

GREGORY E. KALBAUGH, ESQ.
Director and Counsel
Intellectual Property, Trade and Labor
U.S.-India Business Council
U.S. Chamber of Commerce

BRIJESH REGAL
Chief Executive Officer
Apothecaries Limited India

Tutorial Workshop:

Regulatory Registration in India and China
April 26
8:00 AM-12:00 PM

CONTACT INFORMATION

Conference: Joanne Wallace
Phone +1-215-442-6180
email Joanne.Wallace@diahome.org

Tabletop Exhibits: Jeff Korn
Phone +1-215-442-6184
email Jeff.Korn@diahome.org

KEYNOTE SPEAKER

Kenneth I. Kaitin, PhD
Director of the Tufts Center for the Study of Drug Development
Associate Professor of Medicine
Tufts University School of Medicine, Tufts University

Dr. Kaitin is the Director of the Tufts Center for the Study of Drug Development at Tufts University, where he studies national and worldwide trends in pharmaceutical innovation, regulation, and public policy. He is also Assistant Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Dr. Kaitin has written extensively on factors that contribute to the slow pace and high cost of pharmaceutical R&D, and the impact of regulatory and legislative initiatives to speed drug development and approval.

FEATURED SPEAKERS

Marlene Haffner, MD, MPH
Executive Director, Global Regulatory and Intelligence Policy
Amgen, Inc.
Former Director, Office of Orphan Products Development, U.S. FDA

Yogendra Kumar Gupta, MD, MNAS, MBBS
Professor and Head
Department of Pharmacology
All India Institute of Medical Sciences

Chris Israel, MBA
U.S. Coordinator for International Intellectual Property Enforcement
U.S. Department of Commerce

Zili Li, MD, MPH
Director of Clinical Research Operations and Regulatory Policy – Asia Pacific
Merck & Co., Inc.

CONFERENCE OVERVIEW

India and China, two of the world's most populous countries and once considered difficult markets to enter, have taken significant strides as emerging markets in drug development. It is no coincidence over the last decade or more of economic liberalization, and years of unprecedented growth, that India and China are becoming a preferred clinical research destination for multinational pharmaceutical and biotechnology corporations.

The conference aims to provide a detailed analysis of what it takes to conduct clinical trials from a biopharmaceuticals and vaccines perspective in India and China, to address: risk/benefit balance; anecdotal experiences of the multinational pharmaceutical industry in India and China; selection and role of CROs; logistics of operations; clinical trials management; government policies (including IPR issues); and pharmacovigilance.

WHO SHOULD ATTEND

This program will benefit professionals involved in:

- Clinical research and development
- Clinical safety and pharmacovigilance
- Clinical supplies
- Biostatistics
- Data management
- Investigator site management
- Outsourcing management/contract research organizations (CROs)
- Project management
- Medical affairs
- R&D and strategic issues
- Regulatory affairs
- Public policy and law including intellectual property

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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

Accreditation and Credit Designation

Please monitor the DIA website for Continuing Education information.

www.diahome.org

Learning Objectives: At the conclusion of this conference, participants should be able to:

- Summarize methods to make informed decisions about conducting clinical studies from a biopharmaceutical perspective
- Identify the data management, CMC supply chain, operational requirements and CRO infrastructure in India and China
- Discuss the regulatory requirements and implication of conducting these studies in India and China
- Explain government regulation and legal infrastructure in India and China

KEY TOPICS

- Why India and China – Emerging Markets in Biopharmaceutical Development
- Data Management, Supply Chain and Operations of Clinical Research in India and China for Biopharmaceuticals
- Strategic Outsourcing and Partnership with India and China – CRO Infrastructure, Analysis and Performance
- Drug Registration of Biopharmaceuticals/Vaccines in India and China – (Process of drug registrations)
- Government Policy and Regulatory Landscape

WEDNESDAY • APRIL 25

4:00-6:00 PM REGISTRATION

THURSDAY • APRIL 26

7:15-8:00 AM TUTORIAL REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:05 AM INTRODUCTION TO THE FACULTY

Rominder (Romi) Singh, PhD
Executive Director, Global Regulatory Affairs
Amgen, Inc.

8:05-8:35 AM TUTORIAL WORKSHOP

Regulatory Registration in India and China: Multinational Corporation (MNC) Perspective

Raj Long
Executive Director, Asia Pacific-Intercon
Bristol Myers-Squibb Company-WWMG

This session will focus on a practical guide to understanding the regulatory aspects of biopharmaceutical regulatory applications in India and China. During the session we will focus on the following aspects: (1) a background of the biopharmaceutical markets in each country in order to better understand general regulatory philosophies; (2) provide a general regulatory overview; (3) provide detailed review of key components of the process including timing, costs, legal requirements, pre-clinical requisites, CMC requirements, and the like; and (4) new trends in the regulatory process, including adaptive trial designs.

As more pharmaceutical and biotechnology companies are going global, there is an increasing need for knowledge and understanding of regulatory requirements in various geographic regions that offer the potential for development and marketing of these products. India and China hold immense potential not only for traditional pharmaceuticals, but also for the biotechnology industry.

Despite paucity of published regulatory information regarding clinical trials and product registrations in India and China, this topic has so far received only cursory attention. This tutorial aims to provide an insight of the opportunities offered by India, and a broad overview of Indian regulatory scenario. Besides, it will offer in-depth understanding of the country's regulatory nuances, including step-by-step guidance about data requirements to conduct clinical trials in India and China. The discussions will include regulatory challenges likely to be experienced while seeking clinical trial permissions or registration of biotech products in both India and China.

The session will then address the problems commonly encountered during the regulatory process. Lastly, the session will provide several practical suggestions on how to limit time and cost during the process.

8:35 AM-12:00 PM

Regulatory Registration in India and China

Tutorial Instructors:

China
Mark Engel
Chairman
Excel Pharmastudies, China

Jenny Zhang, MD, MHA
Director of Business Development
U.S. Excel PharmaStudies Inc.

India
Brijesh Regal
Chief Executive Officer
Apothecaries Limited India

11:00 AM-1:00 PM MEETING REGISTRATION

12:00-1:00 PM LUNCH

LUNCH ON DAY ONE IS NOT PROVIDED

1:00-1:15 PM WELCOME AND OPENING REMARKS

Romi Singh, PhD
Executive Director, Global Regulatory Affairs
Amgen, Inc.

1:15-2:00 PM KEYNOTE ADDRESS:

Why India and China? – Emerging Markets in Biopharmaceutical Development, Part I

Kenneth I. Kaitin, PhD
Director of the Tufts Center for the Study of Drug Development
Associate Professor of Medicine
Tufts University School of Medicine
Tufts University

This keynote session will further examine the highest stakes for clinical research in India and China in terms of profitability, patient population, shaping economic and regulations through production of safe and efficacious drug development.

2:00-3:00 PM SESSION 1

Is the Current Climate in India and China Conducive to Attract Western Biotechnology Companies?

Panel Discussant

Kenneth I. Kaitin, PhD
Director of the Tufts Center for the Study of Drug Development
Associate Professor of Medicine
Tufts University School of Medicine
Tufts University

Panelists:

Marlene Haffner, MD, MPH
Executive Director, Global Regulatory and Intelligence Policy,
Amgen, Inc.

Fidela Moreno, MD
Executive Director, Global Development Operations, Asia
and Latin America, Amgen, Inc.

Zili Li, MD, MPH
Director of Clinical Research Operations and Regulatory Policy
Merck & Co., Inc.

Yogendra Kumar Gupta, MD, MNAMS, MBBS
Professor and Head
Department of Pharmacology
All India Institute of Medical Sciences, New Delhi

Romi Singh, PhD
Executive Director, Global Regulatory Affairs
Amgen, Inc.

Speaker (China Representative)

Speaker (India Representative)

3:00-3:30 PM REFRESHMENT BREAK

3:30- 5:00 PM SESSION 2

Drug Clinical Trial Experience: India and China

Chairperson

Fidela Moreno, MD
Executive Director, Global Development Operations, Asia
and Latin America, Amgen, Inc.

Leading biopharmaceutical professionals will address their experience on conducting clinical trials in India and China and how it impacts ROW.

Clinical Trial Experience: Global
Fidela Moreno, MD
Executive Director, Global Development Operations, Asia
and Latin America, Amgen, Inc.

Clinical Trial Experience: China
Dayao Zhao, MD, PhD
Head of Clinical Trials
Genzyme Pharmaceuticals

Clinical Trial Experience: India
Speaker Invited

5:00-6:00 PM NETWORKING RECEPTION

FRIDAY • APRIL 27

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM OPENING AND REMARKS

Mark Engel
Chairman
Excel Pharmastudies, China

8:30-10:00 AM SESSION 3

Data Management, Supply Chain and Operations of Clinical Research in India and China

Session Chairperson

Chris Lee
Executive Director
Global Regulatory Affairs and Safety Operations
Amgen, Inc.

High level experts will address the entire drug development process including clinical trial feasibility, IRBs, clinical supplies, data management, import, export and closeout reports.

Data Managementand Clinical Trials in China
Peter Wong, MS, PhM
Director Head of Global Biometrics Application System
Head Global Clinical Document Imaging and Processing
Johnson and Johnson Pharmaceuticals

Supply Chain
Gideon Ong
Director Regional Accounts
World Courier

Headquarters Perspective: Challenges and Opportunities
Speaker Invited

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 4

Regulatory Landscape

Session Chairperson
Zili Li, MD, MPH
Director of Clinical Research Operations and Regulatory Policy – Asia Pacific
Merck & Co., Inc.

This session will deliver information on government policy, regulation and pharmacovigilance. Leading industry speakers will engage and reach for high-level discussion on acceptability of foreign data, GCP inspections and pharmacovigilance.

Regulatory Landscape of U.S. FDA
Marlene Haffner, MD, MPH
Executive Director of Regulatory Affairs for Global Affairs Government
Amgen, Inc.

Clinical and Regulatory Landscape in India
Yogendra Kumar Gupta, MD, MNAMS, MBBS
Professor and Head
Department of Pharmacology
All India Institute of Medical Sciences, New Delhi

Clinical and Regulatory Landscape in China
Zili Li, MD, MPH
Director of Clinical Research Operations and Regulatory Policy – Asia Pacific
Merck & Co., Inc.

12:00-1:30 PM LUNCH

1:30-3:00 PM SESSION 5

Strategic Outsourcing and Partnership with India and China: CRO Infrastructure, Analysis and Performance

Session Chairperson
Romi Singh, PhD
Executive Director, Global Regulatory Affairs
Amgen, Inc.

This session will cover all aspects for CRO selection, qualification and partnership to conduct clinical trials in India and China. Case studies will be presented to help facilitate decision making on the selection of local or global CRO for clinical trial services.

India CRO
Brijesh Regal
Chief Executive Officer
Apothecaries Limited India

China CRO
Mark Engel
Chairman
Excel Pharmastudies, China

Global CRO
Wendy Buckland
Executive Director
Latin America and Asia, PPD Inc

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 6

Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Government Policies

Chairperson
Gregory E. Kalbaugh, Esq.
Director and Counsel
Intellectual Property, Trade and Labor
U.S.-India Business Council
U.S. Chamber of Commerce

This session will address trade-related aspects of intellectual property rights, government regulation and policy, and legal infrastructure in both India and China.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) Protection in India and China: Current Status
Chris Israel, MBA
US Coordinator for International Intellectual Property Enforcement
U.S. Department of Commerce

Intellectual Property Rights in India
Gregory E. Kalbaugh, Esq.
Director and Counsel
Intellectual Property, Trade and Labor
U.S.-India Business Council
U.S. Chamber of Commerce

Intellectual Property Rights in China
James J. Zhu, PhD, JD
Partner
Perkins Coie, LLP

5:00 PM CONFERENCE ADJOURNED

Upcoming DIA Conferences and Training Courses

WORKSHOPS

APRIL 11-13, 2007
QT Issues in Drug Development
The Evolving Science, Practical Issues, and Regulatory Implications
Washington, DC

APRIL 12-13, 2007
Preventive Drug Development: Complexities and Challenges
Bethesda, MD

APRIL 19-20, 2007
Industry and Health Authority Conference on: Oligonucleotide-based Therapeutics
Bethesda, MD

APRIL 26-27, 2007
Clinical Research and Product Registration of Biopharmaceuticals/Vaccines in India and China
San Diego, CA

MAY 10-11, 2007
Protecting Human Subjects in Clinical Investigations from Design to Completion
Washington, DC

MAY 17-18, 2007
SPL Highlights Data Elements: Clinical and Practical Approaches
Washington, DC

JUNE 17-21, 2007
DIA 43rd Annual Meeting
Atlanta, GA

OCTOBER 28-30, 2007
DIA Canadian Annual Meeting
Ottawa, Ontario, CANADA

TRAINING COURSES

APRIL 16-17, 2007
Project Management: New Drug Product Development and Lifecycle Management
Horsham, PA

APRIL 16-17, 2007
Clinical Statistics for Nonstatisticians
Philadelphia, PA

APRIL 16-18, 2007
Drug Safety Surveillance and Epidemiology
Philadelphia, PA

APRIL 23-26, 2007
Regulatory Affairs – Part I: The IND Phase
Part II: The CTD/NDA Phase
West Chester, PA

APRIL 30-MAY 1, 2007
European Regulatory Affairs: An In-depth Review of Registration Procedures in the European Union
Horsham, PA

APRIL 30-MAY 2, 2007
Fundamentals of Clinical Research Monitoring
Chicago, IL

APRIL 30-MAY 2, 2007
Introduction to Good Clinical Practices and Auditing
Chicago, IL

APRIL 30-MAY 2, 2007
Project Management
Chicago, IL

APRIL 30-MAY 3, 2007
The Leadership Experience
Chicago, IL

MAY 7-9, 2007
Advanced Topics in Clinical Research/Drug Development
Philadelphia, PA

MAY 21, 2007
Good Clinical Practices for the Clinical Research Professional
Horsham, PA

MAY 21-23, 2007
Regulatory II: The CTD/NDA Phase
Chicago, IL

AUGUST 6-9, 2007
Regulatory Affairs – Part I: The IND Phase
Part II: The CTD/NDA Phase
Boston, MA

TRAVEL AND HOTEL The most convenient airport is San Diego International Airport and attendees should make airline reservations as early as possible to ensure availability. The Omni San Diego Hotel is holding a block of rooms at the reduced rate below until April 5, 2007, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $245 **Double $245**

Please contact the Omni San Diego hotel by telephone at +1-800-THE-OMNI or 619-231-6664 and mention the DIA event. The hotel is located at 675 L Street, San Diego, California 92101, USA.

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To obtain schedule information and the best fares, call United Airlines's Specialized Meeting Reservations Center at **1-800-521-4041**. ***Make sure you refer to Meeting ID Number 571AK.*** Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! ***All 4 individuals must register and prepay at the same time – no exceptions.*** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

▶ **To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.**

Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

DRUG INFORMATION ASSOCIATION http://www.diahome.org

Horsham, PA, USA
Tel: +1-215-442-6100 • Fax: +1-215-442-6199
email: dia@diahome.org

Basel, Switzerland
Tel: +41-61-225-51-51 • Fax: +41-61-225-51-52
email: diaeurope@diaeurope.org

Tokyo, Japan
Tel: +81-3-5511-1131 • Fax: +81-3-5511-0100
email: diajapan@diajapan.org

MEMBER EARLY BIRD *Register by APRIL 5, 2007* **SAVE $130**

Clinical Research and Product Registration of Biopharmaceuticals/ Vaccines in India and China

Event ID #07012

Omni San Diego Hotel, San Diego, CA, USA

APRIL 26-27, 2007

Half-day Tutorial "Regulatory Registration in India and China"
April 26, 8:00 AM-12:00 PM.

KEY TOPICS

- Why India and China – Emerging Markets in Drug Development and Conducting Clinical Research in India and China: New and Experienced Perspectives
- Logistics and Operations of Clinical Research in India and China for Biopharmaceuticals
- Strategic Outsourcing and Partnership with India and China – CRO Infrastructure, Analysis and Performance
- Drug Registration of Biopharmaceuticals/Vaccines in India and China – (Process of drug registrations)
- Government Policy and Regulatory Environment

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and during receptions (if applicable).

Event information: Contact Joanne Wallace at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.

Tabletop exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For tabletop exhibit space, please check the box below.

❑ **To receive a tabletop exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)

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Registration Fees

If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons and reception and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY *Available on nondiscount member fee only.*	On or before APRIL 5, 2007	After APRIL 5, 2007
Member Fee	US $ 890 ❑	US $1020 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/en/Membership/AboutMembership/AboutMembership**

MEMBERSHIP US $ 130 ❑

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A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

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Charitable Nonprofit/Academia (Full-time)	US $ 625 ❑	US $ 755 ❑

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TUTORIAL
April 26, 8:00 AM-12:00 PM ***Regulatory Registration in India and China*** US $ 375 ❑

❑ To receive a tabletop exhibit application, please check.

CANCELLATION POLICY: On or before APRIL 19, 2007

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $50

Cancellations must be in writing and be received by the cancellation date above. 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. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

- **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.**

❑ **I cannot attend but please keep me informed of DIA's future events.**
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Horsham, PA 19044-3595 USA

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Do not remove mailing label. Please return this entire page. **07012**
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Please check the applicable category:
❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student *(Call for registration information)*

Last Name Check if part of group registration ❑ First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.