6th DIA Regulatory Conference

India, the Upcoming Economy: Encouraging Enforcement of Regulations

ID# 13651 May 23-24, 2013

Courtyard Ahmedabad (Marriott) | Ahmedabad, Gujarat, India

PROGRAM CO-CHAIRS

Hemant Koshia
Commissioner, Food and Drugs Control Administration, Gujarat

K. Anand
President, Global Quality and Regulatory Affairs, Zydus Cadila

PROGRAM COMMITTEE

Rajeev Mathur
Head of Global Regulatory, Ranbaxy Laboratories Limited

Albinus D'sa
Deputy Country Director, US FDA, India

Zoher Sihorwala
Vice President Global Regulatory Affairs Dr. Reddy's Lab

A. Ramkishan
Asst. Drugs Controller, Gujarat, CDSCO

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Senior Manager Regulatory Affairs, GSK

R. L. Vaishya
Joint Commissioner FDCA, Gujarat

Shrenik Shah
Director, Montage Labs

Rajkiran Jain
Vice President – IRA Zydus Cadila

WHO SHOULD ATTEND

Professionals with experience in clinical safety and who are involved in:

- Regulatory Affairs from Government and Industry
- Clinical Research and Development
- Safety and Pharmacovigilance
- Clinical Trial and Project Management
- CMC/Quality (Quality, Manufacturing and Controls)
- QA and QC
- Product Development

INDIA OFFICE
Drug Information Association
A-303, Wellington Business Park 1 | Andheri-Kurla Road, Marol Andheri East, Mumbai 400059

WORLDWIDE HEADQUARTERS
800 Enterprise Road, Suite 200 | Horsham, PA 19044, USA

REGIONAL OFFICES
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China Washington, DC, USA

GUEST OF HONOUR

G. N. Singh
Drug Controller General of India (DCGI)

KEYNOTE SPEAKER

Rajiv Gulati
President Global Pharmaceuticals Business, Ranbaxy Laboratories Limited

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Commissioner, Food and Drugs Control Administration, Gujarat

K. Anand
President Global Quality and Regulatory Affairs, Zydus Cadila

HIGHLIGHTS

This conference brings prominent industry experts, senior management professionals, academicians and regulators together to share the knowledge they've gained from decades of experience and note-worthy contributions to the development of the Indian pharmaceutical industry. While the achievements in reaching global standards in India have been significant, a lot more needs to be done to stay competitive in the world market due to ever-evolving stringency on regulatory enforcements. This conference brings together the best talent in the pharmaceutical world to understand what the challenges are, deliberate how to be prepared to face up to these complexities by learning from the past, and decide proactive measures that could be taken by the industry.

LEARNING OBJECTIVES

This two-day conference offers a unique opportunity for key stakeholders from health authorities, local and multinational pharmaceutical companies, and clinical research to meet and exchange views, discuss topics of interest, and identify focus areas for ongoing efforts to increase patient access to new and improved medicines. This conference will provide a forum to facilitate discussion on common issues in the regulatory and technical areas in India.

All attendees will receive a DIA Certificate of Attendance at the conclusion of the event.

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DAY 1 | THURSDAY, MAY 23, 2013

8.30-9.15 REGISTRATION

9.15-9.30 INTRODUCTION

9.30-10.00 GUEST OF HONOUR

G. N. Singh
Drug Controller General of India (DCGI)

10.00-10.30 KEYNOTE SPEAKER

Rajiv Gulati
President Global Pharmaceuticals Business
Ranbaxy Laboratories Limited

10.30-11.00 TEA AND COFFEE BREAK

11.00-12.00 SESSION 1

Dosage Forms

QbD Approaches in Drug Development

Subramanian Iyer
Associate Vice President
Mylan Laboratories Limited

Regulatory in Aseptic Technologies

M. S. Mahadevan
President and Chief Executive Officer
Biozeen, Millipore

12.00-1.00 SESSION 2

Biologicals

Regulatory Pathway in Biosimilars

Sanjeev Kumar
Senior Vice President
Zydus Cadila

Regulatory Expectations and Industry Needs

Ivy Louis
Founder, Vienni Training and Consulting
Bangalore

1.00-2.00 NETWORKING LUNCH

2.00-3.00 SESSION 3

Medical Devices

Regulatory Aspects of Devices & Drug Combination Products

Daniel Shoukier
Global Regulatory Affairs Director
Biosensors International, Germany

Regulatory Paradigm for Medical Devices Clinical Trials in India

Sumati Randeo
Associate Director, Regulatory Strategy & Policy Advocacy
Asia Pacific, Abott Labs

3.00-3.30 TEA AND COFFEE BREAK

3.30-5.00 SESSION 4

Skill Development

Role of Training of Enhancement of Human Skills

Ivy Louis
Founder, Vienni Training & Consulting
Bangalore

Interface of Academia in Shaping Young Students to Future Industry Challenges

Yusuf Jaliwala
Principal
Indore College of Pharmacy

Business Development in Pharma Industry: Opportunities and Challenges

Alok Sonig
India Head, Senior Vice President, Global Generics
Dr. Reddy's Lab

DAY 2 | **FRIDAY, MAY 24, 2013**

9.15-10.45 SESSION 5

Regulatory Challenges In Emerging Market

Regulatory Challenges in Emerging Markets-Special Emphasis on BRICS

Hasumati Rahalkar
Founder, METINA Consultants

Rajeev Mathur
Head, Global Regulatory Affairs
Ranbaxy Laboratories Limited

Life Cycle Management of Pharmaceuticals in Regulated Market

Zoher Sihorwala
Vice President
Global Regulatory Affairs
Dr. Reddy's Lab

10.45-11.00 TEA AND COFFEE BREAK

11.00-12.30 SESSION 6

APIs

ICH Q11-Challenges in Implementation

Rajiv Desai
President, Quality
Dishman Pharmaceuticals and Chemicals Ltd.

Setting Quality Standards in Drug Substances

Surendra Nath
USP (TBD)

12.30-1.15 LUNCH BREAK

1.15-2.45 SESSION 7

Regulatory Affairs

Challenges in Quality/Regulatory System in Indian Perspective

A. Ramkishan
Assistant Drug Controller
CDSCO, Gujarat

Laboratories Expectations in Regulatory Market Environment

K. Anand
President, Global Quality and Regulatory Affairs
Zydus Cadila

2.45-3.00 TEA AND COFFEE BREAK

3.00-4.30 SESSION 8

Regulatory Affairs - IT Perspective

Regulatory Intelligence

Siddharth Shah
Associate Director, LS R&D Practice
Cognizant

Regulatory Affairs Leveraging Cloud Computing

Vikram Anand
Associate Vice President, Cloud and Commercial Operations
Aris Global

4.30-5.15 PANEL DISCUSSION/FIRE CHAT

Hemant Koshia
Commissioner
Food and Drug Control Administration, Gujarat

A. Ramkishan
Assistant Drug Controller
CDSCO, Gujarat

Zoher Sihorwala
Vice President, Global Regulatory Affairs
Dr. Reddy's Lab

K. Anand
President, Global Quality and Regulatory Affairs
Zydus Cadila

TRAVEL AND HOTEL

Attendees should make airline reservations as early as possible to ensure availability. Courtyard Ahmedabad (Marriott) is holding a block of rooms at the reduced rate below until May 13, 2013 for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single INR 6500 (CP Plan without Taxes), Breakfast and Airport Transfer Included

Courtyard Ahmedabad (Marriott) – Ramdev Nagar Cross Road, Satellite Road, Ahmedabad, 380015 India

Contact Person: Leena Bhindora, Assistant Sales Manager, Cell: +91.90.9901.7743; Tel: +91.79.6618.5098; Fax: +91.79.6618.5299; email: Leena.Bhindora@courtyard.com

MEETING CONTACTS

MEETING MANAGER: Manoj Trivedi, Senior Manager
Marketing and Program Development, DIA (India) Private Limited
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email: Manoj.Trivedi@diaindia.org

Drug Information Association
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Andheri East, Mumbai 400059

CANCELLATION POLICY: On or before MAY 15, 2013

Cancellations must be in writing and received by May 15, 2013. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.

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.

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):*

Member/Nonmember Registration = 3,000 INR • Student Registration = 500 INR

PLEASE CONSIDER THIS FORM AS AN INVOICE

6TH REGULATORY CONFERENCE - India, the Upcoming Economy: Encouraging Enforcement of Regulations
Meeting ID #13651 – May 23-24, 2013 – Courtyard Ahmedabad (Marriott) | Ahmedabad, India

REGISTRATION FEES

Registration fee includes refreshment breaks, and will be accepted by mail/courier.

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

	BASIC RATE (INR)	TAXES (INR)	TOTAL (INR)
INDUSTRY (MEMBER)	8500	1051	❑ INR 9551
INDUSTRY (NONMEMBER)	9000	1113	❑ INR 10113
ACADEMIA	4000	495	❑ INR 4495
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Exhibit Rates: 50,000 INR (One Booth attendee and one Conference pass is the part of package)**

****One booth attendee and one full conference pass is the part of booth package.**

***A limited number of student registrations are available.**

A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Please send completed registration form, copy of student identification, and payment.

REGISTRATION TERMS AND CONDITIONS: Registration form should be duly filled, signed by the authorized person. You are requested to email the duly filled and signed Registration Form first and then courier/mail it along with registration fees on or before 5 working days before the event.

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CRO ❑ Student

❑ Non-Member ❑ Member : Customer ID No.: _____

PLEASE PRINT ALL INFORMATION CLEARLY

PAYMENT INFORMATION

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

Bhavesh Vora

Sr. Executive Accounts, DIA (India) Private Limited
Cell: +91.982.097.2630, Tel: +91.22.6523.0676
email: Bhavesh.Vora@diaindia.org

Degrees: ❑ Dr. ❑ Mr. ❑ Ms.

Last Name (Family Name)

First Name M.I.

Job Title

Affiliation (Company)

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

Postal Code City State Country

Telephone Number Fax Number Mobile Number

email (Required for confirmation) **Signatory**

Payment contact person's Full Name Telephone Number Email

Total Amount Due Organisation PAN no.