5th Regulatory Conference: Evolving Global Regulatory Environment

I.D. #12651 April 13-14, 2012
ITC Maratha, Mumbai

PROGRAM ADVISOR

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Maharashtra State

PROGRAM COMMITTEE

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KEYNOTE SPEAKER

Rajiv Malik
President
Mylan Inc., USA

INTERNATIONAL SPEAKERS

Lawrence Liberti
Executive Director, Centre for Innovation in Regulatory Science (CIRS), UK

Michael Rozycki
Vice President, Regulatory Affairs Asia Pacific, Allergan China

Clemens Laumeier
Director - Emerging Markets, EXTEDO GmbH

Raj Long
Senior Regulatory Consultant

Janis Bernat
Senior Manager, Biotherapeutics & Innovation, IFPMA

PROGRAM CO-CHAIRS

Arun Mishra
Director, Global Regulatory Affairs
Emerging Markets and Asia Pacific
GlaxoSmithKline, UK

Zoher T. Sihorwala
Vice President
Global Regulatory Affairs
Dr Reddy's Lab

Pharmaceutical manufacturers in India are facing many challenges within the domestic and global regulatory environment. These challenges include manufacturing and quality control, testing and packaging. This conference will provide interactive sessions on many of these issues including discussion on strategies to achieve global regulatory compliance.

LEARNING OBJECTIVES

This conference will bring together regulatory professionals, academia and regulators to discuss various aspects of evolving global regulatory landscape particularly around:

- New changes in EU regulatory environment e.g. new variation guideline and implementation, pediatric regulation
- Emerging and evolving biosimilar regulation in India, EU, US, S. Korea, Brazil and Russia
- Focus around Complex Generics and evolving understanding
- Quality and compliance in manufacturing and clinical trials
- Special focus on regulatory affairs' profession and career with Q&A with leading regulatory professionals

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

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DAY 1 | FRIDAY, APRIL 13, 2012

9:00-9:15 AM OPENING CEREMONY

SESSION CHAIRS

Arun Mishra
Director
Global Regulatory Affairs (Emerging Markets and Asia-Pacific)
GlaxoSmithKline, UK

Zoher T. Sihorwala
VP Global Regulatory Affairs
Dr Reddy's Laboratories

9:15-9:45 AM KEYNOTE ADDRESS

Pharmaceutical Industry - From Chemicals to Biologicals... Evolution through Negotiating Regulatory Pathways...

Rajiv Malik
President
Mylan Inc., USA

9:45-10:30 AM PLENARY SESSION

Regulators / Industry—Effective Communication and Work Relationships to Bring Products to the Market Speedily

SESSION CHAIR

K. Anand
COO, Famycare

Albinus D'Sa, PhD
Deputy Director, USFDA

Dr Vinay Nayak
President Technical, Alembic

DCGI - Invited

Head of MHRA Office (TBC)

10:30-11:00 AM TEA BREAK

11:00-12:30 PM SESSION 1

Evolving Regulatory Review Processes—Transparency / Timeliness / Predictability

SESSION CHAIR

Arun Mishra
Director
Global Regulatory Affairs (Emerging Markets and Asia-Pacific)
GlaxoSmithKline, UK

Regulatory agencies across the world share common goal – provide safe, effective and quality medicine to their people. However, regulatory requirement, review processes and timelines vary from one agency to another. Regulatory agencies in established markets (e.g. Europe, US, Japan, Australia etc) are continuously evolving their review processes and practices to bring more predictability and quality in their regulatory review processes.

The session will bring different perspectives on enablers and hinderer of good regulatory review practices.

What are the expectation and requirements of the regulatory review process to deliver the needs today and for the future? A company viewpoint
Arun Mishra
Director
Global Regulatory Affairs (Emerging Markets and Asia-Pacific)
GlaxoSmithKline, UK

Agency Consortia: Evolving work sharing models to enable effective resource utilization and improve patient access to medicines
Lawrence Liberti
Executive Director, Centre for Innovation in Regulatory Science (CIRS), UK

Factors which need to be considered to facilitate a quality, transparent, timely and predictable regulatory review process
Lawrence Liberti
Executive Director, Centre for Innovation in Regulatory Science (CIRS), UK

Prisha Patel
Portfolio Manager, Centre for Innovation in Regulatory Science (CIRS), UK

12:30-1:30 PM NETWORKING LUNCH

1:30-3:00 PM SESSION 2

Negotiating Regulatory Minefields in Drug Development and Registrations in India, Emerging Markets and Developed Markets

SESSION CHAIR

Alberto Grignolo, PhD
Corporate Vice President, Global Strategy
PAREXEL Consulting

The goal of this session is to compare and contrast the contemporary regulatory challenges existing in India, other important emerging markets and the more developed markets (Japan, EU and US), and to identify successful negotiation strategies tailored to each reality. Despite the substantial "regulatory convergence" taking shape around the world today, it is still important to "act locally" to be successful. This session will explore how to do so.

Opportunities and Challenges in Working with Regulators in Developed Markets
Michael Rozycki
Vice President, Regulatory Affairs Asia Pacific
Allergan China

Opportunities and Challenges in Working with Regulators in India
Dr V. V. S. Swaroop Kumar
Incozen

Opportunities & Challenges in working with Regulators in Emerging Markets
Raj Long
Senior Regulatory Consultant

3:00-3:30 PM TEA BREAK

3:30-5:00 PM SESSION 3

Pharmaceutical Industry and Talent Need—Focus on Drug Regulatory Affairs

SESSION CHAIR

Dr R. S. Gaud
Dean, Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management

Indian Pharma Industry is second to US in terms of number of US FDA approved world class facilities. However the question immerges as to what knowledge and talent Industry need? Whether graduates and postgraduates produced by Pharmaceutical Institutions do they meet requirements of Industry? How do we bridge the gap of what is required by the industry and the one catered by academia?

Academia are at a cross road and need support and help to make a road map for future. Human resource development has to be frontal priority for Pharmaceutical Institutions in the country.

Role of Academia in Building Regulatory Affairs Professionals
Dr P. G. Shrotriya
CEO, Pharmaceutical Consultants
Elite Consultancy Services

Industry Expectations while Hiring Pharma Professionals
Kaushik Ray
Vice President, Human Resources
Dr Reddy's Laboratories

Skill Development in Pharmaceutical Sector
Ranga Iyer
National Skill Development

5.00 PM DAY END

DAY 2 | SATURDAY, APRIL 14, 2012

9:00-10:00 AM SESSION 4 PANEL DISCUSSION

Human Subject Protection in Clinical Trials

SESSION CHAIR

Shoibal Mukherjee
Vice President - Medical, Quintiles

This panel discussion will assess patient vulnerabilities and attempt to evaluate the adequacy of systems in place for human subject protection in India. Panelists will be encouraged to suggest ways in which systems for human subject protection can be further strengthened. A sense of the house will be sought to estimate the level of satisfaction among the audience regarding human subject protection in clinical trials underway in the country.

Deven Parmar
Vice President, Global Clinical Research, Wockhardt Ltd

Dr Nandini Kumar
Former Deputy Director General
Senior Grade Co-investigator NIH Project
National Institute of Epidemiology

Urmila Thatte
Head, Department of Clinical Pharmacology
Seth G.S. Medical College, Mumbai

10:00-10:30 AM TEA BREAK

10:30 AM-12:00 PM SESSION 5

Next Generation Generics

SESSION CHAIR

Dr Vinay Nayak
President Technical, Alembic

Overview of Complex Generics, Current Industry Outlook and Challenges
Sanjay Chaturvedi, PhD
Vice President - Sales and Marketing
Dr Reddy's Laboratories

Complex Generics—Regulatory Ease or Regulatory Difficulty
Abhay Muthal
Senior General Manager, Regulatory Affairs
Sun Pharma

Approval of Generics in Japan
Sanjit Singh Lamba
Managing Director & Head, Global Procurement Strategy
Eisai Knowledge Centre

12:00-1:00 PM LUNCH

1:00-2:30 PM SESSION 6

Regulatory Compliance in the Age of Increasing Enforcement

SESSION CHAIR

Amit Khanna, PhD
PH-Dev-TRD - Global Regulatory CMC, India Unit Head
Novartis Healthcare

Quality Assurance in R&D—A Perspective
Dr Shashank Lulay
Senior Vice President, QA
Orchid Chemicals & Pharmaceuticals

Quality by Design—Industry's Hard Work, Regulator's Delight
Dr Amit Biswas
Head, Integrated Product Development
Dr Reddy's Laboratories

Managing External Supply in a Complex Environment
Uma Iyer
Vice President, Quality Operations Leader, Emerging Markets
Pfizer Global Supply, Pfizer

2:30-3:00 PM TEA BREAK

3:00-4:30 PM SESSION 7

Information Technology in Pharmaceutical Regulatory Affairs

SESSION CHAIR

H. G. Koshia
Commissioner, FDCA Gujarat

EVMPD in the context of Regulatory Information Management
Clemens Laumeier
Director - Emerging Markets
EXTEDO GmbH

Information Technologies in Pharmaceutical Academia—Present Challenges and Future Paths
Dr Piysh Trivedi
Vice Chancellor, Rajiv Gandhi Proudyogiki Vishwavidyalaya (RGVP), Bhopal

TBC
H. G. Koshia
Commissioner, FDCA Gujarat

4:30-6:00 PM SESSION 8

Biologics—2020 and Beyond

SESSION CHAIR

This session highlights the strategies and activities governments and industry are taking to further develop biologic medicines, including biosimilars. With viewpoints from expert speakers, we look to the future of biologic medicines, the important issues facing manufacturers today and the impact of new regulations for biosimilars.

SESSION CHAIR

Janis Bernat
Senior Manager, Biotherapeutics & Innovation, IFPMA

Regulatory Perspective on Behalf of the Innovative industry
Dr Chandrasekhar Potkar
Vice-Chairman of the Biotech Committee of OPPI
Director, Medical and Regulatory Affairs, Pfizer Ltd.

Overview of the draft FDA Biosimilar Guidelines and their potential impact for industry
Dr Earl Dye
Director Technical Regulatory Policy & Strategy
Genentech

Overview of the draft FDA Guidance
Yasmin Shenoy
Director - Regulatory Affairs, Sanofi Group

TBC
DCGI (TBC)

6:00-6:15 PM VALEDICTORY AND DAY END

TRAVEL AND HOTEL

Attendees should make airline reservations as early as possible to ensure availability. ITC Maratha is holding a block of rooms at the reduced rate below until March 31, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single INR 7000 | Double INR 8000
Inclusive of taxes, breakfast and airport transfers

The ITC Maratha is located at Sahar, Andheri (E), Mumbai 400 099, Maharashtra, India.
Phone: 022.2830.3030; Fax: 022.2831.5545

Contact Person: Vinayak Polekar
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MEETING CONTACTS

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CANCELLATION POLICY: On or before MARCH 12, 2012
Cancellations must be in writing and received by March 12, 2012. 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. If the 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 = INR 3,000 • Student Registration = INR 500

PLEASE CONSIDER THIS FORM AS AN INVOICE

5th Regulatory Conference: Evolving Global Regulatory Environment
Meeting I.D. # 12651 – April 13-14, 2012 – ITC Maratha, Mumbai

REGISTRATION FEES

Registration fee includes refreshment breaks, luncheons, and conference material.

Join DIA now to qualify to save on future events and to receive all the benefits of membership. To see all the benefits of DIA membership, visit www.diahome.org and click on Membership.

	BASIC RATE	TAXES	TOTAL
Standard Membership	1768	182	❑ INR 1950
Student Membership*	453	47	❑ INR 500

MEMBER			
	BASIC RATE	TAXES	TOTAL
Industry	6640	410	❑ INR 7050
Academia	3814	236	❑ INR 4050
Student*	2402	148	❑ INR 2550

NONMEMBER (Inclusive of Membership)			
	BASIC RATE	TAXES	TOTAL
Industry/Govt/CRO	8408	592	❑ INR 9000
Academia	5582	418	❑ INR 6000
Student*	2855	195	❑ INR 3050

EXHIBITS				
	BASIC RATE	TAXES	TOTAL	INCLUDES
Tabletop	60000	6180	❑ INR 66180	One full conference pass + one Tabletop attendee pass
Banner	15000	1545	❑ INR 16545	One full conference pass only

***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.

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

❑ Non-Member ❑ Member : Customer ID* No.: _____ (mandatory)

PLEASE FILL ALL INFORMATION CLEARLY, IN CAPITALS LETTERS

Degrees: ❑ Dr. ❑ Mr. ❑ Ms.

Last Name (Family Name)

First Name

Job Title

Organisation

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.

*Please refer to your Membership card for the Customer ID no.

PAYMENT INFORMATION

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

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