Future Perspectives in Pharmacovigilance

ID# 12650 March 3-4, 2012

The Park, Bangalore, India

PROGRAM CO-CHAIRS

Moin Don
Executive Director
PVCON, Pharmacovigilance Consulting Services

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Director, Pharmacovigilance Asia Pacific
Baxter Healthcare

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JSS College of Pharmacy Medical College Hospital, Mysore

R K Giridhar
Vice President, BPO Pharma Services
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Dr Chitra Lele
Chief Scientific Officer
Sciformix Corp

INTERNATIONAL SPEAKERS

Stewart Geary
Vice President and Deputy Director
of Corporate Regulatory Compliance, Safety and QA
Eisai Co. Ltd. Japan

Dr Sidney Kahn
Principal Scientist
Sciformix Pharmacovigilance Services

Dr Sumit Munjal
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KEYNOTE SPEAKERS

Dr Y K Gupta
Department Head, Clinical Pharmacology
All India Institute of Medical Sciences

Stewart Geary
Vice President and Deputy Director of Corporate Regulatory Compliance, Safety & QA
Eisai Co. Ltd. Japan

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HIGHLIGHTS

Ask the Experts
Join international pharmacovigilance experts for an open Q&A session to discuss your most difficult pharmacovigilance challenges.

DIA Special Interest Area Communities (SIACs)

FEATURED TOPICS

- Safety Management during Early Drug Development program
- US and EU Safety Regulation Updates - New FDA Rule / DSURs
- Safety and Regulatory Writing
- Medical Devices Vigilance
- Panel Discussion on Schedule Y and Empowerment to ECs/IRBs
- India as Pharmacovigilance Outsourcing Destination
- Safety during Clinical Trials through Medical Monitoring
- Integrating Pharmacovigilance in Medical and Para Medical Curriculum
- Utility of Cloud computing in Pharmacovigilance Database Domain

WHO SHOULD ATTEND

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

- Pharmacovigilance
- Clinical research
- Risk management
- Compliance
- Medical information
- Regulatory affairs
- Academia
- Pharmacology

LEARNING OBJECTIVES

At the conclusion of this conference, participants will be able to:

- Explain key aspects of current global safety reporting requirements for prescription and over-the-counter drugs
- Discuss new pragmatic approaches to pharmacovigilance as proposed by the CIOMS working group
- Describe the regulatory agency clinical safety and pharmacovigilance inspection program in the US, Europe, and Japan
- Identify best practices for quality assurance in post marketing pharmacovigilance and clinical safety

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

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DAY 1 | SATURDAY, MARCH 3, 2012

8:00-9:00 AM REGISTRATION

9:00-9:15 AM OPENING REMARKS

Opening Remarks

Moin Don
Executive Director
PVCON

Dr Vivek Ahuja
Director
Pharmacovigilance Asia Pacific
Baxter Healthcare

9:15-9:35 AM KEYNOTE ADDRESS 1

The Lives and Times of Pharmaceutical Companies in Managing Ever Increasing Safety Regulations

Stewart Geary
Vice President and Deputy Director
Corporate Regulatory Compliance, Safety and QA
Eisai Co. Ltd. Japan

9:35-10:00 AM KEYNOTE ADDRESS 2

The Indian Pharmacovigilance Scenario – An Introspection

Dr Y K Gupta
Department Head, Clinical Pharmacology
All India Institute of Medical Sciences

10:00-10:15 AM BREAKFAST

10:15 AM-12:30 PM SESSION 1

The Vision For Pharmacovigilance

10:15-11:00 AM
Ensuring High Returns Through Investments in the Future of Pharmacovigilance
Dr Vivek Ahuja
Director, Pharmacovigilance Asia Pacific
Baxter Healthcare

11:00-11:45 AM
PV Systems in China and Japan
Stewart Geary
Vice President and Deputy Director of
Corporate regulatory Compliance, Safety and QA
Eisai Co. Ltd. Japan

11:45-12:30 PM
Integrating Drug Safety Knowledge into the DNA of the Medical Educational System
Dr Urmila Thatte
Head of Department, Clinical Pharmacology
Seth G.S. Medical College, Mumbai
Dr Y K Gupta
Department Head, Clinical Pharmacology
All India Institute of Medical Sciences

12:30-1:30 PM LUNCH

1:30-4:45 PM SESSION 2

Regulatory Updates

1:30-2:30 PM
Panel Discussion: Indian Regulation/Schedule Y
Moin Don
Executive Director
PVCON

2:30-3:15 PM
An Overview of the New EU PV Regulation: impact on PV Processes
Sumit Verma
Head of PV, EU Operations
APCER

3:15-3:30 PM TEA

3:30-4:15 PM
The Practical implications of New FDA Rule and DSURs
Dr Sidney Kahn
Principal Scientist
Sciformix Pharmacovigilance Services

4:15-4:45 PM
European Pharmacovigilance Regulatory Perspective and Latest Developments
Dr Sumit Munjal
Consultant Physician (Oncology)
Global Medical Safety
Johnson & Johnson
A divison of Janssen-Cilag Ltd , J & J, UK

4:45-5:45 PM SESSION 3

Technology Updates

4:45-5:15 PM
Online Signal Management - A System Based Approach
Ravinder Singh
APAC Director – HSGBU, Sales Consulting
Oracle Health Sciences

5:15-5:45 PM
Application of Cloud Computing to Fortify the Science of Pharmacovigilance
Vikram Anand
Head agOnDemand
ArisGlobal

DAY 2 | SUNDAY, MARCH 4, 2012

9:00-10:30 AM SESSION 4

Industry Perspective – Outsourcing

9:00-9:30 AM
Global PV Outsourcing – Trends and Challenges
Madhur Rathaur
Director
PWC's PRTM Management Consulting

9:30-10:00 AM
Setting Up Case Processing Unit
Dinesh Kasthuril
Director - Pharmacovigilance Services
Sciformix Technologies

10:00-10:30 AM
Ensuring Quality Through Metrics and SLA Challenges in a Case Processing Environment
Shrish Sherlekar
Group Head, Life Sciences Practice
TCS

10:30-10:45 AM BREAKFAST

10:45 AM-1:00 PM SESSION 5

Industry Perspective – Best Practices

10:45-11:15 AM
People Management Strategies
R K Giridhar
Vice President, BPO Pharma Services
Accenture

11:15-12:00 PM
Elements For Successful Pharmacovigilance Agreements
Angela Pitwood
Vice President Pharmacovigilance
Indipharm Inc., US

12:00-12:30 PM
Safety and Regulatory Writing
Gunjan Shah
Project Manager, Medical Writing
Sciformix Technologies Ltd.

12:30-1:00 PM
Signal Detection Through Conventional Methods and Data Minning
Ajoy Roy
Senior Medical Director
PAREXEL India

1:00-1:45 PM LUNCH

1:45-3:45 PM SESSION 6

PV Through Drug Development Phase

1:45-2:45 PM
Panel Discussion: Empowering ECs/IRB for Safety Assessment
Dr Chitra Lele
Chief Scientific Officer
Sciformix Corp

2:45-3:15 PM
Safety Consideration During Early Phase Drug Development
Nipom Deka
Global Pharmacovigilance Regional Head - Asia Pacific
Glenmark

3:15-3:45 PM
Challenges in Ensuring Protocol Compliance and Patient Safety
Aparna Kalsekar
Head – Medical Services
SIRO Clinpharm Pvt. Ltd.

3:45-4:00 PM TEA

4:00-5:00 PM SESSION 7

PV Stake-Holders Perspective

4:00-4:30 PM
Spontaneous Reporting in Hospital Set Up
Prof Parthasarthi Gurumurthy
Professor and Head, Department of Clinical Pharmacy
JSS College of Pharmacy Medical College Hospital, Mysore

4:30-5:00 PM
Practicing PV during General Practice
Dr Sandeep Bavdekar
Professor and Head, Department of Pediatrics
TN Medical College & BYL Nair Hospital

5:00 PM CONFERENCE ADJOURNED

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TRAVEL AND HOTEL

Attendees should make airline reservations as early as possible to ensure availability. The Park Bangalore is holding a block of rooms at the reduced rate below until February 10, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single/Double INR 6000 + Taxes

is located at 14/7 Mahatma Gandhi Road, Bangalore 560042, India

Contact Person: Sudhanshu Singh, Phone: +91.80.2559.4666 Fax: +91.80.2559.4667
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MEETING CONTACTS

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CANCELLATION POLICY: On or before JANUARY 15, 2012

Cancellations must be in writing and received by January 15, 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.

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 = INR 3,000 • Student Registration = INR 500

PLEASE CONSIDER THIS FORM AS AN INVOICE

FUTURE PERSPECTIVES IN PHARMACOVIGILANCE

Meeting I.D. # 12650 – March 3-4, 2012 – The Park Bangalore, Bangalore, INDIA

REGISTRATION FEES

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

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.

MEMBER			
	BASIC RATE	TAXES	TOTAL
Industry	5698	352	❑ INR 6050
Academia	3767	233	❑ INR 4000
Student*	2825	175	❑ INR 3000

NONMEMBER (Inclusive of Membership)			
	BASIC RATE	TAXES	TOTAL
Industry	7466	534	❑ INR 8000
Academia	5582	418	❑ INR 6000
Student*	2825	175	❑ INR 3000

***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

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

PLEASE PRINT ALL INFORMATION CLEARLY

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.

PAYMENT INFORMATION

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

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