"PV Fast Forward" - Technology , Pace, Priority.

24th & 25th March 2017
Hotel Lalit, Andheri East, Mumbai

DIA

PROGRAM CHAIR

Moin Don
CEO and President
PVCON

PROGRAM VICE CHAIR

Krishna Bahadur Singh
Senior Vice President
Safety& Risk Management
Business Unit
ARISGlobal LLC
&
Representative Director,
AGKK, Tokyo, Japan

PROGRAM COMMITTEE

Achint Kumar Gupta
EU QPPV
Safety & Benefit-Risk Management
Biogen

Jamal Anwar Baig
Country Head- Pharmacovigilance
Merck Sharp & Dohme

J Vijay Venkatraman
Managing Director & CEO,
Oviya MedSafe Pvt Ltd

Mangesh Kulkarni
Head Pharmacovigilance
Tata Consultancy Services

Rajesh Jain
Director Operations & Business Solutions
Cognizant

Retesh Kumar
Senior Business Consultant and Engagement Lead
Tata Consultancy Services

Supriya Desai
Director Pharmacovigilance
Sciformix

Vivek Ahuja
VP Global Pharmacovigilance
ArisGlobal

Technological advancements are rapidly impacting the way pharmacovigilance obligations will be fulfilled by marketing authorization holders. The modus operandi of conducting pharmacovigilance operations is expected to change significantly by the year 2020. Automation, artificial intelligence, machine learning, cognitive computing, pro-active pharmacovigilance are shaping the new paradigm of the safety world. Achieving compliance at a lower cost and higher quality is much closer as a goal today than it was ever before. PV fast forward is a meeting of minds that celebrates this cause, and provides an opportunity to cross learn through this journey.

This conference aspires to bring together thought leaders representing many of the stakeholders of pharmacovigilance to deliberate the current best practices, deliberations on Automation in PV, Label Management & Risk Management and many other niche topics, with the focus being on pharmacovigilance and related professionals in India. The two-day conference will ensure enough opportunity to interact with speakers and colleagues from the entire spectrum of the pharmacovigilance domain in India."

Program Highlights

- Label Management & Risk Management
- Automation in PV
- Compliance Management in PV
- Latest Regulations in PV
- Cutting Edge Technologies to Handle Safety Data
- Importance of Technology in bringing about higher Patient safety

Learning Objectives

At the end of the Conference the participants should be able to:

- Comprehend multiple facets of global drug safety concepts along with insights on Indian pharmacovigilance
- Understand how new technologies can help in improving adverse event reporting and processing of safety data
- Discuss the advancements in pharmacovigilance in the European Union and how it influences the global drug safety

MEETING MANAGER

Manoj Trivedi
Senior Manager, Business Development
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AGENDA

Day 1 | Friday, 24th March

8:30 – 9:30 **REGISTRATION**

9:30 – 10:00 **OPENING CEREMONY**

10:00 – 10:30 **KEYNOTE PRESENTATION – Transforming Pharmacovigilance through Technology**

Krishna Bahadur Singh
Senior Vice President - Safety& Risk Management Business Unit
ARISGlobal LLC & Representative Director, AGKK, Tokyo, Japan

10:30 – 11:00 **Tea / Coffee Break**

11:00 – 13:30 **Session 1 - Automation in PV**

Session Chair
Rajesh Jain
Director Operations & Business Solutions
Cognizant

Speakers
11:00 – 11:45 | **Robotics & Digital PV Solutions – Way Forward**
Rajesh Jain
Director Operations & Business Solutions
Cognizant

11:45 – 12:30 | **Artificial Intelligence - use in Pharmacovigilance**
Srinivas Padmanabhuni
Chief Mentor
Tarah.AI (Tarah Technologies)

12:30 – 13:30 | **Panel Discussion - 'New Draft GPvP Guidelines for Indian Pharma Industry'**
Moderator
Moin Don
CEO and President
PVCON

Panelists
Jamal Anwar Baig
Country Head - Pharmacovigilance
Merck Sharp & Dohme

Ujwala Naik
Country Safety Head
Janssen Cilag

Mazhar Maruf
General Manager - Global Pharmacovigilance
Glenmark Pharmaceuticals Limited

13:30 – 14:00 **LUNCH**

14:00 – 16:00 **SESSION 2 - PV Outsourcing / Offshoring**

Session Chair
Krishna Bahadur Singh
Senior Vice President
Safety& Risk Management Business Unit
ARISGlobal LLC & Representative Director, AGKK, Tokyo, Japan

Speakers
14.00 – 14.30 | **Pharmacovigilance of Medical Devices – Challenges & Opportunities in India**
Sanjeev Miglani
Vice President-PV and Clinical safety North America and Global Medical Affairs
APCER LIFESCIENCES

14:30 – 16:00 | **Panel Discussion - Offshoring / Outsourcing Dealing with Authorization**
Moderator
Krishna Bahadur Singh
Senior Vice President -Safety& Risk Management Business Unit
ARISGlobal LLC & Representative Director, AGKK, Tokyo, Japan

Panelists
Seema Jaitly
Managing Director
Essjay Solutions Ltd

Vineet Shastri
Sr. Director & Head
Lifecycle Safety Medical Services
Global Delivery Network
QuintilesIMS

Deepa Arora
Global PV Head
Lupin

Gurpreet Singh
Head Vendor Management
Novartis

Retesh Kumar
Senior Business Consultant and Engagement Lead
Tata Consultancy Services

Achint Gupta
EU QPPV Safety & Benefit-Risk Management
Biogen

16:00 – 16:30 **Tea / Coffee Break**

AGENDA

16:30 – 18:00 **SESSION 3 - Label Management & Risk Management**

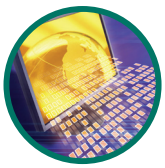
Session Chair
Moin Don
CEO and President
PVCON

Speakers
16:30 – 17:15 | **The Science & Process behind Global Labelling as Risk Management Tool**
Sarath Mundra
Team Lead Global Labelling
Novartis

17:15 – 18:00 | **Journey of data from case processing to Risk Management via Signals**
Suhasini Sharma
Director, Medical Affairs
Sciformix

18.00 **DAY END**

DIA India 2017 Events



Digital Disruption in Life Sciences - a Look at NextGen CDM

April 21-22 | Bengaluru

The pivot of the Life Sciences industry is a shift from cost optimization to technology driven innovations which is an enabler for Research & Development. With advent of digital disruption, this shift is more prominent in the rather conservative industry like ours. This conference aims to bring case studies and thought leadership on how NextGen Clinical Data Services can deliver better business outcomes which impact quintessential indicator of 'speed to market' aimed towards improved quality of outcome and enhanced regulatory compliance.

Exploring the Scientific Art of Medical Writing: Blending Complexity with Simplicity

June 16-17 | Mumbai

As the world becomes more complex, writers struggle to play a fine balancing act between dealing with more complex challenges such as authoring complex protocols, drafting risk management plans, publication planning, authoring aggregate reports, drafting comprehensive economic and outcomes literature reviews, to stepping down the complexity a notch, trashing the jargon and developing the art of authoring lay language summaries, understanding the value and nuances of QC'g safety narratives and balancing the freedom of expression with the importance of compliance. It is a tight rope walk, with the need to stay abreast with the latest tools and technologies, evolving regulations and yet not lose the fine art if writing.

Deciphering the Why, When and How of Risk Based Monitoring

September 22-23 | Mumbai

The latest ICHE6 R2 guidance has driven even the nay-sayers to focus on developing RBM strategies. Without experience and expertise to support the same, one may actually end up adding risk to a study. The industry has an urgent need to understand the strategies involved in RBM, including the development of the IQRMP, the de-velopment of a risk scoring model, the identification of the KRIs, the SDV strategy, site-tiering strategy, the road-blocks and the pre-emptive measures, the identification of the proof points and the latest regulations and the tools and technologies involved. In addition, this conference will touch on the role of the risk based monitor and the criticality of a well outlined change management strategy.

AGENDA

Day 2 | Saturday, 25th March

9:30 – 11:15 **Session 4 - Latest Regulations in PV**

Session Chair
Jamal Anwar Baig
Country Head- Pharmacovigilance
Merck Sharp & Dohme

Speakers
9:30 – 10:15 | **EU regulations - Update**
Achint Kumar Gupta
Sr. Director, EU QPPV
Safety & Benefit-Risk Management
Biogen

10:15 – 11:15
E2B R3 implementation
Mangesh Kulkarni
Head Pharmacovigilance Offering
Tata Consultancy Services

PV Data Analytics
Retesh Kumar
Senior Business Consultant and Engagement Lead
Tata Consultancy Services

11:15 – 11:45 **Tea / Coffee Break**

11:45 – 14:00 **Session 5 - Compliance Management**

Session Chair
Rajesh Jain
Director Operations and Business Solutions
Cognizant

Speakers
11.45 – 12.30 | **Risk Minimisation Activities & Evaluation of Effectiveness**
Seema Jaitly
Managing Director
Essjay Solutions Ltd

12.30 – 13.15 | **A risk based approach to real time compliance**
Savitha Hanuman
VP. Compliance
Accenture India

13.15 – 14.00 | **Indian Pharmacovigilance – Where do we stand today**
J Vijay Venkatraman
Managing Director & CEO
Oviya MedSafe Pvt. Ltd.

14:00 – 14:45 **LUNCH**

14:45 – 16:15 **SESSION 6 - PV Miscellanea**

Session Chair
J Vijay Venkatraman
Managing Director & CEO
Oviya MedSafe Pvt Ltd

Speakers
14.45 – 15.30 | **Text mining and its relevance in Pharmacovigilance**
Kailash Chanduka
Director- Testing Shared Services
Aris Global Software Pvt. Ltd.

15.30 – 16.15 | **Protecting patients safety in INDIA – Challenges & Opportunities in implementing Pharmacoepidemiology**
Sanish Davis
Country Head & Sr. Medical Director
Covance

16:15 – 16:30 | **Conference Wrap up**

16:30 **Tea / Coffee**

"PV Fast Forward" - Technology , Pace, Priority.
Event I.D. 17650 | 24-25 March 2017 | Mumbai, India

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CANCELLATION POLICY: ON OR BEFORE MARCH 15, 2017

- Cancellations must be in writing and received by MARCH 15, 2017. 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 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

For more details, please visit www.DIAglobal.org

REGISTRATION FEES FOR TWO DAYS CONFERENCE (*Registration fee includes refreshment breaks and luncheons.)*

Early Bird on or before 3rd March 2017 (Early Bird Confirmation - Subject to Payment Realization)

	BASIC RATE (INR)	SERVICE TAX 15 %(INR)	TOTAL INR
INDUSTRY MEMBER	9000	1350	10350 ❑
INDUSTRY NON- MEMBER	11000	1650	12650 ❑
ACADEMIA / GOVERNMENT	8000	1200	9200 ❑
STUDENT	5000	750	5750 ❑

After 4th March 2017

	BASIC RATE (INR)	SERVICE TAX 15 %(INR)	TOTAL INR
INDUSTRY MEMBER	10000	1500	11500 ❑
INDUSTRY NON- MEMBER	12000	1800	13800 ❑
ACADEMIA / GOVERNMENT	8000	1200	9200 ❑
STUDENT	5000	750	5750 ❑

GROUP DISCOUNT : REGISTER 10 FROM YOUR COMPANY AND RECEIVE THE 11TH FREE!

DIA MEMBERSHIP
Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diahome.org and click on Membership for more details

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

DRUG INFORMATION ASSOCIATION
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PAYMENT DETAILS
Account Name: DIA (INDIA) PRIVATE LIMITED
Account No: 061010200024611
bank Name: AXIS BANK LIMITED
Branch Name: Dhiraj Baug, Near Hari Niwas Circle, LBS Marg, Thane (W) – 400602
IFSC Code: UTIB0000061
MICR Code: 400211013
Swift Code: AXISINBB061

PAYMENT INFORMATION
Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:
Bhavesh Vora
Senior Executive Accounts
bhavesh.vora@diaglobal.org | cell : +91 98 2097 2630

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

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name First Name M.I. Please check one: ❑ Mr. ❑ Ms. ❑ Prof. ❑ Dr.

Job Position Affiliation (Company) ❑ Business Address ❑ Home Address

Address (Please write your address in the format required for delivery to your country.) City Postal Country/Region

Address

Telephone Number Fax Number Mobile Number (Required) Email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.

DIA India Pharmacovigilance Conference Support Opportunities

Solo Opportunity

Principal Supporter (One)

300000 INR

- This is the **'SOLO'** opportunity means only one company can participate as a principal supporter
- Free Booth (Octanorm) Size: 3X2 Meters
- Four (4) full free conference access and two (2) booth attendee passes
- Logo on Registration desk
- Standee at the Entrance Area with company name and logo as a principal supporter(6x3Feet)
- Standee with logo and promotional content at preconference area projecting the company as a Principal Supporter (6x3 Feet)
- Logo panel on Coffee Kiosk
- Reserve seating arrangement for the delegates

Gold Supporter

250000 INR

- Complimentary Tabletop
- Three (3) complimentary full conference access passes one(1) booth attendee passes
- Logo on registration desk
- Standee at the entrance area
- One standee in preconference area with the logo and promotional content (6x3Feet)
- Complimentary Tabletop: **6x2 ½ Feet**

DIA India Pharmacovigilance Conference Support Opportunities

Silver Support

150000 INR

- Two standee (6x3 Feet) in Preconference Area Projecting as a silver supporter
- Two (2) Full Conference Access Passes
- Logo on registration desk

Table Top

75000 INR

Table Size:
- 6x2 ½ Feet Skirted Table will be provided by DIA
- You can place your promotional material; Pop Up, Standees or Flyers
- One full complimentary conference access and one booth attendee passes

**Artwork of standees should be provided by the company within the given time frame and for any additional services; LCD Screen or any other accessories company has to pay in actuals