USFDA–EMA– CDSCO–DIA Multicentre GCP Workshop

12th & 13th May 2017 | St Regis, Mumbai
15th & 16th May 2017 | Taj Krishna, Hyderabad

DIA and US FDA will host a 2-day workshop on guidance and polices from the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and Central Drugs Standard Control Organization (CDSCO). GCP inspections related to the quality of clinical trials in Mumbai and Hyderabad. Additional topics discussed at the workshop will include, Data Integrity and BE Study. Interact with experts from USFDA, CDSCO, EMA and industry, who will share experiences and views of the global GCP environment.

Program Highlights

- Retrospect and Prospect of India GCP
- Overview of FDA's Bioresearch Monitoring Program
- EMA and National GCP Inspection: Systems and Procedures
- What to Expect during Regulatory Inspections
- Role of Ethics Committee in driving GCP Compliance at trial sites
- India USFDA’s Focus on Data Integrity – Lessons Learned
- Triggers for Inspections and Selection of Inspections
- GCP as a Quality Standard in Clinical Research
- GCP Inspections and Inspection Findings
- A Review of Recent Regulatory Actions
- Root Cause Analysis: When Something Goes Wrong
- Case studies
- Panel Discussion

PROGRAM CO-CHAIR

Sean Kassim
Director, Office of Study Integrity and Surveillance
Office of Translational Science Center for Drug Evaluation and Research
USFDA

Ramakrishnan Sundaram
Director Regulatory Affairs EPD
Abbott Healthcare

MEETING MANAGER

Manoj Trivedi
Senior Manager, Business Development
DIA (India) Private Limited | cell: +91 98.1977.7493 | manoj.trivedi@diaglobal.org

DIA India Pvt. Ltd.
Office Number 250, Unit No 1, Level 2, B Wing | Times Square, Andheri Kurla Road (Andheri East, Mumbai 400059, INDIA) +91 22 6608 9588 (tel) | +91 9029098844 (cell) | www.DIAglobal.org | India@DIAglobal.org

DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing/Shanghai, China | Horsham, PA, USA | Mumbai, India | Tokyo, Japan
Day 1

08:00-09:00  **Registration**

09:00-09:15  **Welcome Remarks**
**DIA**

09:15-09:30  **Opening Remarks**
**Leslie Ball**
Assistant Commissioner of International Programs & Deputy Director - Office of International Programs (OIP)
USFDA

09:30-10:00  **Overview of FDA’s Bioresearch Monitoring Program – Roles & Responsibilities of Sponsor**
**Jennifer Adams**
Assistant Country Director
USFDA India Office

10:00-10:30  **Tea Break / Coffee break**

10:30-11:00  **Retrospect and Prospect of India GCP**
Speaker Invited - CDSCO

11:00-11:30  **EMA GCP Inspection: Systems and Procedures**
**Laura Pioppo**
Scientific Administrator
EMA Committees & Inspections Department
EMA

11:30-12:00  **CT Inspections and Observations Analysis**
**Shehnaz Vakharia**
Managing Director
ADAMAS Consulting Pvt. Ltd.

12:00-12:30  **ICH GCP addendum Overview**
**Mumbai**
**Arun Bhatt**
Consultant - Clinical Research & Development

**Hyderabad**
**Pawandeep Kaur Dhawan**
Associate Medical Director
Clinical Development Services Agency

12:30-13:30  **Luncheon**

13:30-14:00  **Triggers for Inspections and Selection of Inspections**
**Angela Del Vecchio**
EU Member State Representative
AIFA – Italian Medicine Agency

14:00-14:30  **What to Expect during Regulatory Inspections**
**Sam H. Haidar**
Deputy Director
CDER
Office of Study Integrity and Surveillance (OSIS)
Division of Generic Drug Bioequivalence Evaluation
USFDA

14:30-15:00  **Tea Break / Coffee break**

15:00-16:00  **Case Study – GCP Inspection – EMA & EU Member State**
**Laura Pioppo**
Scientific Administrator
EMA Committees & Inspections Department
EMA
&
**Angela Del Vecchio**
EU Member State Representative
AIFA – Italian Medicine Agency

16:00-17:00  **Case Study – BE Laboratory**
**Sam H. Haidar**
Deputy Director
CDER
Office of Study Integrity and Surveillance (OSIS)
Division of Generic Drug Bioequivalence Evaluation
USFDA

17:00-17:30  **Open Hour – Q & A**
Day 2

09:00-09:30  **Role of Ethics Committee in driving GCP Compliance at trial sites**

Mumbai
**Urmila Thatte**
Professor and Head - Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital

Hyderabad
**P Usha Rani**
Professor and Head,
Dept of Clinical Pharmacology and Therapeutics,
Nizam's Institute of Medical Sciences

09:30-10:00  **India USFDA's Focus on Data Integrity – Lessons Learned**

Sam H. Haidar
Deputy Director
CDER
Office of Study Integrity and Surveillance (OSIS)
Division of Generic Drug Bioequivalence Evaluation
USFDA

10:00-10:30  **Tea Break / Coffee break**

10:30-11:00  **GCP as a Quality Standard in Clinical Research**

Leslie Ball
Assistant Commissioner of International Programs & Deputy Director - Office of International Programs (OIP)
USFDA

11:00-11:30  **GCP Inspections and Inspection Findings**

Speaker Invited - CDSCO

11:30-12:00  **GCP Inspections and Inspection Findings - EMA perspective**

Laura Pioppo
Scientific Administrator
EMA Committees & Inspections Department
EMA

12:00-12:30  **GCP Inspections at the sponsor site and findings identified**

Angela Del Vecchio
EU Member State Representative
AIFA – Italian Medicine Agency

12:30-13:00  **Luncheon**

13:30-14:00  **Excellence and Continuous Improvement of Clinical Research Processes: Sponsor-CRO Oversight**

Subashri Shivkumar
Head Clinical Development Services, India & Sri Lanka,
QuintilesIMS

14.00-14:30  **Root Cause Analysis: When Something Goes Wrong**

Chandrika Arora
Founder & CEO
QMANTRA

14:30-15:00  **Tea Break / Coffee break**

15:00-16:00  **Panel Discussion : GCP inspections in India-Perspectives from Key Stakeholders**

Panelists
USFDA Representative
CDSCO Representative
EMA Representative
Laura Pioppo
Scientific Administrator
EMA Committees & Inspections Department
EMA

Angela Del Vecchio
EU Member State Representative
AIFA – Italian Medicine Agency

Industry
Suresh Menon
CSO
Novartis

EC Member
Mumbai
**Urmila Thatte**
Professor and Head - Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital

Hyderabad
**P Usha Rani**
Professor and Head,
Dept of Clinical Pharmacology and Therapeutics,
Nizam’s Institute of Medical Sciences

Investigator

16:00-17:00  **Q&A**
VENEUE:

Mumbai, St. Regis
462, Senapati Bapat Marg, Lower Parel, Mumbai - 400013, India
T +91.22.6162 6057  |  F +91.22.6162.8888
CONTACT: Renita Kothari, Accounts Manager
M +91.8879791364  |  e-mail : Renita.Kothari@stregis.com

Hyderabad, Taj Krishna
Road No: 1, Banjara Hills, Hyderabad – 500 034, Telangana, India
Ph: 91 40 6629 3340  |  Fax: 91 40 6666 1313
CONTACT: Zeeshan Kazi, Catering Sales Co-ordinator
M +91.8806048940  |  e-mail : kazi.zeeshan@tajhotels.com

MEETING MANAGER
Manoj TRIVEDI, Senior Manager, Business Development
DIA (India) Private Limited
cell: +91.98.1977.7493  |  manoj.trivedi@diaglobal.org

CANCELLATION POLICY:

MUMBAI: ON OR BEFORE APRIL 26TH, 2017
HYDERABAD: ON OR BEFORE APRIL 28TH, 2017

- Cancellations must be in writing and received by APRIL 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.)

<table>
<thead>
<tr>
<th>category</th>
<th>BASIC RATE (INR)</th>
<th>SERVICE TAX 15 % (INR)</th>
<th>TOTAL INR</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUSTRY MEMBER</td>
<td>13000</td>
<td>1950</td>
<td>14950</td>
</tr>
<tr>
<td>INDUSTRY NON- MEMBER</td>
<td>15000</td>
<td>2250</td>
<td>17250</td>
</tr>
<tr>
<td>ACADEMIA / GOVERNMENT</td>
<td>12000</td>
<td>1800</td>
<td>13800</td>
</tr>
</tbody>
</table>

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

ONLINE REGISTRATIONS:
Visit our website www.diaglobal.org

CHEQUE / DRAFT
Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:
Bhavesh Vora
Senior Executive Accounts  |  bhavesh.vora@diaindia.org

DRUG INFORMATION ASSOCIATION
Office No. 250, Unit 1, Level 2, B Wing,
Times Square, Andheri Kurla Road,
Andheri East, Mumbai 400059
tel: +91 22.6608 9588  |  email: india@diaglobal.org

PAYMENT DETAILS
Account Name: DIA (INDIA) PRIVATE LIMITED
Account No: 0610102000024611
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)MQS 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.