USFDA–EMA– CDSCO-DIA Multicentre GCP Workshop

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

in collaboration with

DIA FDA EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH CDSCO

PROGRAM COMMITTEE

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

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

Jennifer Adams
Assistant Country Director
USFDA India Office

Laura Pioppo
Scientific Administrator
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EMA

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

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Senior Director-Global Clinical Trial Operations
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AVP - Analytical Sciences, Biologics
Aurobindo Pharma Ltd.

Gaurav Mathur
Director & Head, Regulatory Affairs
Clinical Development Services
QuintilesIMS

Suresh Kankanwadi
Vice President
Dr. Reddy's Laboratories

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
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MEETING MANAGER

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AGENDA

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 **Retrospect and Prospect of India GCP**

Speaker Invited - CDSCO

10:30-11:00 **Tea Break / Coffee break**

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**

AGENDA

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

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

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

Subashri Shivkumar
Head Clinical Development Services, India & SriLanka,
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**

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Event I.D. 17655 | St Regis, Mumbai | 12th & 13th May 2017
Event I.D. 17656 | Taj Krishna, Hyderabad | 15th & 16th May 2017

VENUE:

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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.)*

	BASIC RATE (INR)	SERVICE TAX 15 %(INR)	TOTAL INR
INDUSTRY MEMBER	13000	1950	14950 ❑
INDUSTRY NON- MEMBER	15000	2250	17250 ❑
ACADEMIA / GOVERNMENT	12000	1800	13800 ❑

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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

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PAYMENT DETAILS
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Job Position | Affiliation (Company) | ❑ Business Address ❑ Home Address

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Address

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