USFDA–EMA–CDSCO–DIA GCP Multicentre Workshop

May 3–4 | Mumbai
May 7–8 | Hyderabad
May 10–11 | Bengaluru

DIA and U.S. Food and Drug Administration will host a 2-day workshop on guidance and policies from the US Food and Drug Administration (USFDA), European Medicines Agency (EMA) and Central Drugs Standard Control Organization (CDSCO). This joint program offers a unique opportunity to hear from expert regulators from the West (USFDA and EMA) and the CDSCO on all on the same platform in Mumbai, Hyderabad and Bengaluru.

This two-day workshop will have Sessions on GCP, Biosimilar, Case Studies and Panel discussions.

OBJECTIVE

The objective of this workshop is to disseminate Agencies' current thinking and hear Industry view point on hot burning issues and promote active dialogue during the workshop so that both the agencies and Industry have feedback to work on moving forward.

PROGRAM CO-CHAIR

Letitia Robinson
Country Director
India Office
U.S. Food and Drug Administration

Ramakrishnan Sundaram
Director Regulatory Affairs
ABBOTT

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USFDA–EMA–CDSCO–DIA GCP Multicentre Workshop

May 3–4 | Mumbai
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PROGRAM COMMITTEE

Sam Haidar
Senior Science Advisor
Center for Drug Evaluation and Research (CDER)
Office of Study Integrity and Surveillance (OSIS)
U.S. Food and Drug Administration

Kristan Callahan
International Relations Specialist
BIMO and Medical Devices
India Office
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European Medicines Agency

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K Bangarurajan
Joint Drugs Controller
CDSCO

Anirban Roy Chowdhury
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MSD Pharmaceuticals

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Aurobindo Pharma Ltd (Biologics Division)

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Dr. Reddy's Laboratories Ltd.

Subashri Shivkumar
Sr. Director and Head Clinical Development Services India and Sri Lanka
IQVIA

Vinu Jose
Associate Vice President
Head Clinical Development & Medical Affairs
Intas Pharmaceuticals Ltd. (Biopharma Division)

AGENDA | Day 1

08:00-09:00 **REGISTRATION**

09:00-09:15 **WELCOME REMARKS**

DIA

09:15-09:30 **OPENING REMARKS**

USFDA

09:30-10:00 **HIGHLIGHTS OF BA/BE REGULATIONS FOR EXPORT - AN OVERVIEW**

Mumbai
P B N Prasad
Deputy Drug Controller (India)
CDSCO - West Zone

Hyderabad
A K Pradhan
Deputy Drug Controller (India)
CDSCO - HQ

Bengaluru
K Bangarurajan
Joint Drug Controller (India)
CDSCO - HQ

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

10:30-11:30 **UPDATES ON REGULATORY SCIENCE**

10:30-11:00 Highlights of India's new Clinical trial regulations

Mumbai
P B N Prasad
Deputy Drug Controller (India)
CDSCO - West Zone

Hyderabad
A K Pradhan
Deputy Drug Controller (India)
CDSCO - HQ

Bengaluru
K Bangarurajan
Joint Drug Controller (India)
CDSCO - HQ

11:00-11:30 ICH GCP addendum overview
Divakar Kolli
Sr. Manager – Clinical Quality Assurance
Cipla Limited

11:30-12:30 USFDA Inspections & Observations : Findings from Indian and Global Sites

Jennifer Adams
Consumer Safety Officer
India Office
U.S. Food and Drug Administration

GCP Inspections – Overview of inspection findings (including comparison with findings from sites in India)
EMA SPEAKER

Inspections and Inspection Findings

Mumbai
P B N Prasad
Deputy Drug Controller (India)
CDSCO -West Zone

Hyderabad
A K Pradhan
Deputy Drug Controller (India)
CDSCO - HQ

Bengaluru
K Bangarurajan
Joint Drug Controller (India)
CDSCO - HQ

12:30-13:30 Luncheon

13:30-15:00 **PANEL DISCUSSION – BUILDING AN EFFECTIVE STRATEGY FOR VENDOR OVERSIGHT THROUGH RISK BASED APPROACH**

Mumbai
Moderator: TBD

Panelists

Milind Nadgouda
Director
Quality and Compliance,
RIVERARK LIMITED

Shehnaz Vakharia
Managing Director
ADAMAS Consulting Pvt

Partha Chatterjee
Head –Clinical Operations
SIRO Clinpharm

Hyderabad
Moderator
Parisa Asvadi
VP - Regulatory Sciences
Aurobindo Pharma Ltd.

Panelists

Milind Nadgouda
Director
Quality and Compliance,
RIVERARK LIMITED

Chandrika Arora
Managing Director
QMATRA

Prabhat Kumar
Sr. Compliance Manager - QA
PAREXEL

Kamaldeep S Grover
VP & Head - QA
VIMTA

Bengaluru
Moderator
Anirban Roy Chowdhury
Sr. Director-Global Clinical Trial Operations
MSD Pharmaceuticals

Panelists

Milind Nadgouda
Director
Quality and Compliance,
RIVERARK LIMITED

Chandrika Arora
Managing Director
QMATRA

Partha Chatterjee
Head –Clinical Operations
SIRO Clinpharm

AGENDA | Day 1

15:00-15:30	Tea Break / Coffee break
15:30-16:30	**CASE STUDY – USFDA**
	Sam Haidar Senior Science Advisor CDER Office of Study Integrity and Surveillance (OSIS) U.S. Food and Drug Administration **Jennifer Adams** Consumer Safety Officer India Office U.S. Food and Drug Administration
16:30-17:30	**OPEN HOUR – Q & A**

AGENDA | Day 2

09:00-09:30 **QUALITY CULTURE – HOW DOES IT RELATE TO PATIENT SAFETY?**

Mumbai
P B N Prasad
Deputy Drug Controller (India)
CDSCO - West Zone

Hyderabad
A K Pradhan
Deputy Drug Controller (India)
CDSCO - HQ

Bengaluru
K Bangarurajan
Joint Drug Controller (India)
CDSCO - HQ

09:30-10:30 **PANEL DISCUSSION: ROLES AND RESPONSIBILITIES OF SPONSORS, CROS, INVESTIGATORS AND ETHICS COMMITTEES IN MAINTAINING THE QUALITY CULTURE**

Mumbai
Moderator
Narendra Maharaj
Vice President
Lupin

Panelists

Suneela Thatte
VP Global Operations
IQVIA

Chirag Trivedi
Director & Head
Clinical Study Unit
Sanofi

Anand Easwariah
Head – Medical Affairs and Regulatory Department
Syngene International Limited – Clinical Development

Divakar Kolli
Sr. Manager – Clinical Quality Assurance
Cipla Limited

Urmilla Thatte
Professor and Head
Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital

Hyderabad
Moderator
K. Umamaheshwar
AGM & Head -Clinical Dept. & Operations
AET Laboratories Private Limited

Panelists

Suneela Thatte
VP GLobal Operations
IQVIA

Vaibhav Salvi
Head - Project Management and Strategic Initiatives,
Clinical Study Unit
Sanofi India and South Asia

Anand Easwariah
Head – Medical Affairs and Regulatory Department
Syngene International Limited - Clinical Development

Divakar Kolli
Sr. Manager – Clinical Quality Assurance
Cipla Limited

Chandana Pal
Accreditation & Quality Systems In-Charge
Apollo Research & Innovations (ARI)

Jugal Kishore Kadel
Principal Investigator
CARE Hospital

Bengaluru
Moderator:
Shenaz Khaleeli
Director
Pharmaleaf India Pvt. Ltd.

Panelists

Charu Gautam
Senior Director,
Head Early Clinical Development Asia Pacific
IQVIA

Vaibhav Salvi
Head - Project Management and Strategic Initiatives,
Clinical Study Unit
Sanofi India and South Asia

Anand Easwariah
Head – Medical Affairs and Regulatory Department
Syngene International Limited - Clinical Development

Divakar Kolli
Sr. Manager – Clinical Quality Assurance
Cipla Limited

T K Sumathy
Principal Investigator
M S Ramiah Hospital

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

11:00-11:30 **FDA'S BIOSIMILAR PROGRAM**

Sam Haidar
Senior Science Advisor
CDER
Office of Study Integrity and Surveillance (OSIS)
U.S. Food and Drug Administration

11:30-12:00 **BIOSIMILAR DEVELOPMENT AND BIOANALYTICAL STRATEGY FOR EMA CLINICAL STUDIES**

12:00-13:00 Luncheon

AGENDA | Day 2

13:00-14:00 **PANEL DISCUSSION –"LEVERAGING DIGITAL TECHNOLOGY IN CLINICAL TRIALS"**

Mumbai
Moderator
Shubhangi Desai
Associate Director
Clinical Operations
Abbott

Nixon Patel
Founder and CEO
Kovid Inc

Chirag Trivedi
Director & Head
Clinical Study Unit
Sanofi

Jayathirtha M G
Principal Sales Consultant
APAC Solutions Consulting
Oracle Health Sciences

A G Unnikrishnan
Endrocrinologist
Chellaram Diabetes Institute

Hyderabad
Moderator
Ramakrishnan Sundaram
Director
Regulatory Affairs
Abbott

Nixon Patel
Founder and CEO
Kovid Inc

Vaibhav Salvi
Head - Project Management
and Strategic Initiatives
Clinical Study Unit
Sanofi India and South Asia

Bhaskar Nellipudi
Consulting Practice Director
Oracle Health Sciences

Bengaluru
Moderator
Ramakrishnan Sundaram
Director
Regulatory Affairs
Abbott

Nixon Patel
Founder and CEO
Kovid Inc

Vaibhav Salvi
Head - Project Management
and Strategic Initiatives
Clinical Study Unit
Sanofi India and South Asia

Jeyaseelan Jeyaraj
Director
Health Sciences, Asia Pacific
Oracle Health Sciences

14:00-14:45 **CROSS CUTTING NON COMPLIANCES OBSERVED AT BE STUDIES ON BOTH CLINICAL AND ANALYTICAL PART-2017 TO DATE**

Elham Kossary
Technical Officer (Inspector)
Prequalific tion Team – Medicines
Regulation of Medicines and Health Technologies
World Health Organization

14:45-15:15 Tea Break / Coffee break

15:15-16:15 **CASE STUDY – EMA**

16:15-16:30 **WORKSHOP WRAP UP**

USFDA–EMA–CDSCO–DIA GCP Multicentre Workshop

Event I.D. 18651, 18652, 18657 | May 3–4 | Mumbai | May 7–8 | Hyderabad | May 10–11 | Bengaluru

☐ May 3-4 | **Taj Lands End**, Mumbai Bandstand, Bandra (West), Mumbai – 400050, Maharashtra, India
Pradyumna Taneja, pradyumna.taneja@tajhotels.com | +91 22 666 87282

☐ May 7-8 | **Novotel Hyderabad Convention Centre & Hyderabad International Convention Centre**, Novotel & HICC Complex, (Near Hitec City), P.O. Bag 1101, Cyberabad Post Office, HYDERABAD - 500 081, INDIA
Vikas Pal, vikasp@hicc.com | Mobile: (+91) 9966024006

☐ May 10-11 | **JW Marriott Bengaluru**, 24/1, Vittal Mallya Road, Bengaluru – 560001
Siddharth Sundaram, siddharth.sundram@marriott.com | +91 8884494073

MEETING MANAGER
Manoj TRIVEDI, General Manger, Marketing and Projects
DIA (India) Private Limited
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CANCELLATION POLICY: ON OR BEFORE APRIL 25, 2018

- Cancellations must be in writing and received by April 25, 2018. 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

Online registrations: visit our website www.diaglobal.org

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INDUSTRY NON- MEMBER	12000	2160	14160 ❑
ACADEMIA / GOVERNMENT	8000	1440	9440 ❑
STUDENT	5000	900	5900 ❑

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STUDENT	5000	900	5900 ❑

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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.

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@diaglobal.org
DIA India Pvt. Ltd.
Office No. 250, Unit 1, Level 2, B Wing, Times Square, Andheri Kurla Road, Andheri East, Mumbai 400059
tel: +91 22.6608 9588 | cell: +91 98.2097.2630

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

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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)

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