DIA India ICH Day 2019

Enhancing Clinical Trial Outcomes with ICH

30th August, 2019 | Taj Lands End | Mumbai, India

PROGRAMME COMMITTEE

C. Michelle Limoli
Senior International Health Science Advisor
US FDA

Ramesh Jagannathan
Associate Vice President - R&D
Biocon Ltd.

Anupama Ramkumar
CEO and Principal Consultant
Arkus Research Pvt. Ltd.

Seema Pai
Director - India Cluster
Global Site & Study Operations
Clinical Development & Operations
Pfizer

Ashwani Pandita
General Manager
Quality Management and Training, Clinical Research Operations
Glenmark Pharmaceuticals

Prabhat Kumar
Head- Pharma Quality
Quality Governance Organization
Accenture

Sonika Sharma Shah
Head - Regulatory Affairs
Amgen

Today, the Indian pharmaceutical industry supplies approximately 20% of the world's generic drugs and has the largest number of FDA-approved manufacturing facilities outside of the US. This industry has evolved during the past decade into innovative drug development, including new chemical and biological entities, biosimilars, and innovative differentiated products. At the same time, as healthcare costs continue to rise across the world, so does the global need for affordable, innovative healthcare. Against this backdrop, DIA India aims to create an initiative that will address the clinical and regulatory aspects of drug development, through a comprehensive single day workshop on the latest ICH guidelines and developments relevant for India.

Objective

The objective of this program is to provide a common platform for ICH trainers, regulatory authorities, academia, investigators, service providers, and the Indian biopharmaceutical industry, to deliberate upon and understand ICH guidelines and the most recent updates, impacting the drug development spectrum including key clinical, regulatory and quality aspects.

Take a look at our key topics for the event and expected participation:

Key Focus Areas

- Introduce ICH Vision for Harmonized Global Drug Development Standards
- Evaluate Recent ICH Regulatory Reforms and Their Impact on the Global Regulatory Landscape
- Principles for Design, Conduct and Control of Next Generation Trials With E8
- Risk Based Approaches to Monitoring- Implementing E6(R2)
- Real World Impact of Technology On Clinical Trials- Are We Prepared For This Change?
- Harmonization of Regulatory Reforms And ICH Implementation – The Way Forward

Key Functions and Departments Participating

- Clinical Research Professionals
- Regulatory Affairs
- Scientific Affairs
- Quality and Compliance Management Experts
- Medical Affairs
- Drug Safety Professionals
- General Management
- Program Management Professionals

Support and Exhibit Opportunities Open!

FOR FURTHER INFORMATION, PLEASE REACH OUT TO:

Pradeep Dass
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AGENDA

8:00 – 9:00	Registration
9:00 – 9:30	**Opening Ceremony**
9:30 – 10:15	Keynote Presentation **GLOBAL VISION FOR HARMONIZED DRUG DEVELOPMENT: USING SCIENTIFIC FOUNDATIONS TO CREATE ENABLING REGULATORY FRAMEWORK** **Dhananjay Bakhle** Executive Vice President - Medical Research Lupin Ltd.
10:15 – 11:00	PANEL DISCUSSION **ICH SPECIAL FORUM- ICH COMPLIANCE AND HOW DOES INDIA REGULATORY LANDSCAPE SUPPORT THESE INITIATIVES?** Session Moderator **Sonika Shah** Head-Regulatory Affairs, Amgen Panelists **Chirag Trivedi** Clinical Study Unit Cluster Head -India and SEA Sanofi **Kavita Singh** Mission Director National Biopharma Mission BIRAC **Chirag Desai** Director and Sr. Consultant Medical Oncology Vedanta Institute of Medical Sciences **Sivakumar Vaidyanathan** General Manager Clinical Operations Glenmark Pharmaceuticals
11:00 – 11:30	Tea/Coffee Break

Session # 1 OUTLOOK FOR EFFECTIVE TRIAL MANAGEMENT- ROLE OF ICH E8

SESSION CHAIR

Ramesh Jagannathan
Associate Vice President, R&D
Biocon Ltd.

Seema Pai
Director- India Cluster
Global Site & Study Operations
Clinical Development & Operations
Pfizer

11:30 – 12:15	**RISK BASED APPROACHES TO DESIGN, CONDUCT AND CONTROL OF CLINICAL TRIALS WITH E8** **Sanish Davis** Senior Medical Director, CVMER Head, Global Clinical Trial Operations, India Covance
12:15 – 13:00	OPEN FORUM DISCUSSION **DEVELOPING A PRACTICAL cQMS - CONCEPTUAL AND PRACTICAL FRAMEWORK FOR CLINICAL TRIALS** Moderator **Himanshu Shah** Director - Clinical Research MSD Speakers **Kashyap Pathak** Head - Clinical Alembic Pharmaceuticals **Bina Naik** Chief Operating Officer CBCC Global Research **Shrinivas Savale** CEO, AIC - LMCP Foundation L.M. College of Pharmacy **Partha Chatterjee** Head Clinical Research & CTSM SIRO Clinpharm Pvt. Ltd.
13:00 – 14:00	Networking Lunch

AGENDA

Session# 2 – QUALITY AND RISK MANAGEMENT WITH Q9 AND Q10

SESSION CHAIR

Ashwani Pandita
General Manager Quality Management and Training - Clinical Research Operations
Glenmark Pharmaceuticals

Prabhat Kumar
Head- Pharma Quality
Quality Governance Organization
Accenture

14:00 – 14:45 **TOOLS AND STRATEGIES FOR DYNAMIC RISK ASSESSMENT AND IDENTIFYING CRITICAL ISSUES**

Anita Kanishk
Associate Director - QA, Biologics Clinical Development
Dr. Reddy's Laboratories

14:45 – 15:30 **EFFECTIVE AND PRACTICAL RISK MANAGEMENT OPTIONS FOR COMPUTERISED SYSTEM VALIDATION**

Anupama Ramkumar
CEO and Principal Consultant
Arkus Research Pvt Ltd

15:30 – 16:00 Tea/Coffee Break

Session # 3 – E6(R2) IMPROVING DRUG DEVELOPMENT AND PATIENT ACCESS WITH TECHNOLOGY

SESSION CHAIR

Anupama Ramkumar
CEO and Principal Consultant
Arkus Research Pvt Ltd.

Sonika Shah
Head-Regulatory Affairs
Amgen

16:00 - 16:45 **RISK BASED MONITORING APPROACHES WITH E6(R2)**

Debjit Chakrabarti
Director- Risk Based Monitoring
IQVIA

16:45 – 17:45 OPEN FORUM DEBATE

REAL WORLD IMPACT OF TECHNOLOGY ON CLINICAL TRIALS AND PATIENT ACCESS- ARE WE PREPARED FOR THIS CHANGE?

- IS TECHNOLOGY DRIVING IMPROVED PATIENT ACCESS?
- E-PATIENT DIARY
- VIRTUAL TRIALS
- IMPACT OF SOCIAL MEDIA

Moderator

Ramesh Jagannathan
Associate Vice President -R&D
Biocon Ltd

Panelists

Shivani Acharya
Associate Director
Clinical Development and PV
Abbott

Shankar Arun
Vice President
Informatics
PAREXEL International

Chirag Desai
Director and Sr. Consultant
Medical Oncology
Vedanta Institute of Medical Sciences

Rachna Malik
Head Global Operations and Platform Solutions - Life Sciences
Tata Consultancy Services

17:45 Closing Remarks

DIA India ICH Day 2019 : Enhancing Clinical Trial Outcomes with ICH
Event I.D. 19661 | 30th August, 2019 | Mumbai, India

VENUE:
TAJ LANDS END
SOUJANYA ASHWINI
ASSISTANT MANAGER – CATERING SALES
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MEETING MANAGER
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CANCELLATION POLICY: ON OR BEFORE AUGUST 15, 2019

- Cancellations must be in writing and received by August 15, 2019
- 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

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

	Basic Rate (INR)	Service Tax 18 %(INR)	Total INR
Early Bird on or before 13th August, 2019 (Subject to Payment Realization)			
Industry Member	6000	1080	7080 ❑
Industry Non-Member	7000	1260	8260 ❑
Academia / Government	6000	1080	7080 ❑
Student	5000	900	5900 ❑
Standard Rate from 13th August, 2019 onwards			
Industry Member	7000	1260	8260 ❑
Industry Non-Member	8000	1440	9440 ❑
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You agree that your personal data will be transferred to DIA in the US.

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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:
Vinita Shetty
Finance Manager , vinita.shetty@diaglobal.org
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Office No. 250, Unit 1, Level 2, B Wing, Times Square, Andheri Kurla Road, Andheri East, Mumbai 400059
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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.

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