

# 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

Sr. Manager - Marketing & Business Development  
DIA (India) Private Limited  
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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

### DISCLAIMER

The views and opinions expressed in this training session and associated training materials are those of the individual presenter and should not be attributed to the International Council for Harmonisation (ICH) organization, its members, officers, employees, participants, observers or volunteers

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**

**Pradeep Dass**  
Sr. Manager - Marketing & Business Development  
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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.
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- 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

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|   | Basic Rate (INR) | Service Tax 18 %(INR) | Total INR                     |
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| <b>Early Bird on or before 13th August, 2019</b> (Subject to Payment Realization) |                  |                       |                               |
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You agree that your personal data will be transferred to DIA in the US.

**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.

**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](mailto:vinita.shetty@diaglobal.org)  
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**PAYMENT DETAILS**

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Account No: 061010200024611  
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Branch Name: Dhiraj Baug, Near Hari Niwas Circle, LBS Marg, Thane (W) – 400602  
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