INDIAN SOCIETY FOR CLINICAL RESEARCH

12th Annual Conference

Clinical Research Advancing the Frontiers of Health

February 15-16, 2019, New Delhi

Pre-Conference Workshops – February 14, 2019

Workshop - Career opportunities in Clinical Research and Associated fields

Speakers Profile

Ms. Pooja Mahajan
Sr. Local Trial Manager
Global Clinical Operations India
Johnson & Johnson Private Limited

Ms. Pooja Mahajan
Sr. Local Trial Manager
Global Clinical Operations India
Johnson & Johnson Private Limited

- Pooja Mahajan has about a dozen years of experience in the field of clinical research, managing clinical trials on various therapeutic indications, with pharmaceuticals as well as CROs from across the globe.
- She has successfully lead teams through US FDA & DCGI inspections.
  Pooja is the recipient of the prestigious Study Manager of the year award by the Indian society for Clinical Research.
- She has also authored articles on various topics related to clinical research. You could refer to these in the PICR - indexed in PubMed.
  She is currently employed with Johnson & Johnson Private Limited as a Senior Local Trial Manager.
- Pooja is also an active member of the Training council of the ISCR.

Dr. Shekhar Dawkhar

MHA, PMP

Dr. Shekhar Dawkhar

Covance

MHA, PMP

Project Director (APAC) , Enterprise Client Solutions

Dr. Shekhar Dawkhar is a Post-Graduate in Health Administration having a combined work experience of more than 18 years - 3 years' in epidemiology research/ community health projects followed by more than 15 years of industry experience in different aspects of Clinical Research such as Clinical Operations, Project Managements, Clinical Strategy & Design, Business Operations and Enterprise Client Solutions across global clinical projects in multiple therapeutic areas . He has worked with multiple organizations like Pfizer, Amgen and is presently employed with Covance in their Enterprise Client Solutions function as Project Director, Asia Pac . Shekhar is also active in industry forums and co-chair of the Training Council, Indian Society of Clinical Research and also honorary faculty at Academy of Clinical Excellence, Bombay College of Pharmacy and Tata Memorial Hospital.

Mr. Kedar Nayak

Area Manager- RMEA and AP, Global In-Country Clinical Operations

Mr. Kedar Nayak
GSK Pharmaceuticals
Area Manager- RMEA and AP, Global In-Country Clinical Operations

- Joined GSK India in 1996 as a medical representative and subsequently moved to Clinical Operations in 2004 and have been holding a variety of clinical research roles of increasing seniority including Clinical Research Manager for Oncology at India LOC since 2010, Acting Head of Clinical Operations at Vietnam LOC and Head of Clinical Operations India since September 2015. Regional RBM Champion for the RMEA and AP Region.
- Currently working as the Area Manager_RMEA and AP.
- Master degree in biochemistry and MBA in human resources.
- At work, I love being a part of a team which challenge the obvious/status quo. This helps me challenge myself and foster self and team development.
- Lives in Mumbai blessed with two 2 lovely daughters. Spend most of my weekends running around with them, reading and listen to music.

Mrs. Shilpa Raut

Senior Global Training Manager

Mrs. Shilpa Raut
Senior Global Training Manager
Trial Monitoring Organization (TMo)
MEDICAL PH, Novartis Healthcare Private Limited (India)

Shilpa Raut is a post-graduate in Pharmacy – Quality Assurance Program having a total work experience of 23 years. 7 years as a Lecturer in Pharmaceutical colleges and more than 15 years of experience in different aspects of clinical research such as Clinical Operations, Clinical Services, Quality Assurance and Training in Pharma and CRO Industry. Presently, employed with Novartis in their Trial Monitoring and Excellence Function as a Senior Global Training Manager and responsible for training, setting processes and strategic change management planning for Clinical Research Professionals of more than 3000 associates across Novartis Global Trial Monitoring Organization.

Dr. Gaurav Mathur

PhD

Dr. Gaurav Mathur, PhD
IQVIA RDS (India) Pvt. Ltd.
Director, India Regulatory Affairs, &
Head APAC cRSU
Clinical Development Services

- Gaurav Mathur is a doctorate in Biotechnology from National Chemical Laboratory, Pune, and is currently working with a global and leading Contract Research Organization (CRO) called IQVIA (formerly known as Quintiles) as the Director- Regulatory Affairs and & Head - Central-RSU APAC. His major responsibilities at IQVIA include; advice to pharmaceutical and biotechnology companies on the regulatory strategy for various regulatory submissions in India for the new and marketed, drugs/devices/FDCs, biologics, and biosimilars; and delivering services through centralized Regulatory and Start Up (cRSU) team to 13 Asian countries.
- Gaurav is based in Bangalore, and has an overall 20 years of experience encompassing academics & healthcare industry, R&D, managing preclinical studies, strategic regulatory planning and post-approval product maintenance
- Prior to joining IQVIA in 2010, Gaurav has held senior regulatory and managerial positions at INC Research and Biocon Ltd. He started his career in Industry after completing post-doctoral research at SUAS, Sweden and NCL, Pune, as Scientific Manager with Biocon Ltd. where he was part of the Molecular Biology team in Research & Development.
- Within IQVIA, Gaurav has also served as the Head APAC, Global Regulatory Affairs, setting up the team and processes in Bangalore for regulatory services like, CMC writing, CTD Module 3 & 4 writing, Variation filing, Label updates, Gap analysis, primarily for INDs/NDAs and marketed products.
- Additionally, he supports internal and global stakeholders and clients with regulatory strategy and advice for all types of products and therapies.
- He is an active member of ISCR for past decade and is currently serving as the Co-Chair of the Regulatory Council of the Indian Society of Clinical Research (ISCR).

Sachin Satija

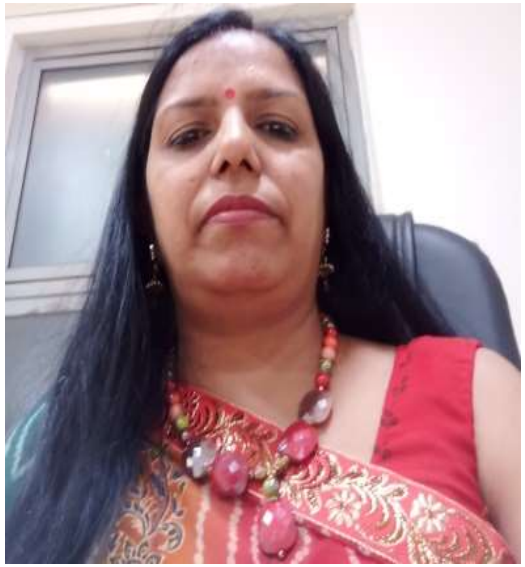
Sr. Director-Quality Assurance, Asia Pacific
Syneos Health

Sachin Satija
Sr. Director-Quality Assurance | Asia Pacific
Syneos Health

- Sachin Satija has over 20 years of experience, in the clinical research industry, five of which have been in the pharmaceutical industry and 15 years in the CRO industry including Phase I , Phase II to III and BA/BE centers.
- Most of her time has been spent in establishing and managing global quality assurance teams to ensure quality and excellence. She has been central to the planning and execution of global audit programs in the organizations. She has extensive experience in hosting inspections of various Regulatory Agencies like FDA, EMEA, DCGI,ANVISA and PMDA (Japan Regulatory Authority).
- She has been involved in leading harmonization activities subsequent to integration of companies in her current and prior organization. She also has international training related experience and has been significant contributor to the process improvement initiatives within her organizations.

Ms. RINKU DAHIYA

M.Sc BioPhysics, M.Sc Clinical Research & MBA in Marketing



- Over 13 years' cross functional expertise: (10 years' experience in Clinical research & 3 years in Business operations)
- Clinical Research
- Site Management
- Implementation
- Safety reporting
- Regulatory Affairs
- Data Management
- Statistical Analysis
- Teaching in Clinical Research
- Constitution & Convening of Ethics Committee
- Scholastics
- Certified NABH Assessor from QCI.
- Certified CRA from ACRP.
- M.Sc. (Clinical Research) & MBA (Marketing) from I.C.R.I, Dr M.G.R. University in 2006 with 72.0%.
- M.Sc. (Biophysics) from Dr Baba Sahib Ambedkar University in 1997 with 70.4%.
- B.Sc. (Micro, Chemistry, Zoology) from Dr Baba Sahib Ambedkar University in 1995 with 64%.
- Carrier Contour - Started Career as CRA in 2006 with Jubiliant Clinsys and worked with Elililly, Abbott Vascular Pvt. Ltd. Worked as lecturer in Clinical Research for ICRI & Indraprastha Apollo Hospital. Became the Asst. course Coordinator and administrator at Apollo Hospital & education Research Foundation. Moved to Apollo Research & Innovations and worked as EC administrator, further got promoted to Sr. Research & EC Administrator. Currently working as Clinical Trial Manager & Site Head at Apollo Research & Innovations, Indraprastha Apollo Hospital.

Ms. RINKU DAHIYA

M.Sc BioPhysics, M.Sc Clinical Research & MBA in Marketing

Apollo Research & Innovations, Indraprastha Apollo Hospital.

Bindu Anil Narang

Practice Director, Scientific Writing & Regulatory Affairs, Sciformix

- Global Head- managing the service lines of aggregate safety and risk management (ASRM) and regulatory affairs; contributing to business development, including new business & mining existing accounts
- Implementing and promoting use of consistent, efficient and quality processes to meet timelines and deliverables according to requirements and standard operating procedures, and assume accountability for the deliverables
- Ensuring compliance of operations with governing regulatory requirements
- Creating, maintaining and assuming accountability for a culture of high customer service
- Providing leadership to establish and grow the ASRM and regulatory affairs service areas at Sciformix
- Handling all resource projections and manage resource requirements and utilization for all service delivery activities
- Supporting executive management on all aspects of execution and business development
- Ensuring delivery of services meets or exceeds Service Level Agreements
- Directing activities of the groups and track status of projects, providing overall project management
- Responsible for the top line revenue associated with the service areas.
- Responsible for bottom line and margins of the service areas.
- Use metrics to track performance with respect to quality and timelines for service areas
- Implement process & productivity improvements as appropriate to improve operational efficiency
- Act as the Client Engagement Manager/Account Manager if required; Support process transition when needed
- Support business development group In preparing marketing collateral, by participation in client interactions and contributing to proposals
- Groom and mentor the delivery leadership of the organization to meet and exceed customer needs
- Share best practices across departments

Bindu Anil Narang

Practice Director, Scientific Writing & Regulatory Affairs, Sciformix

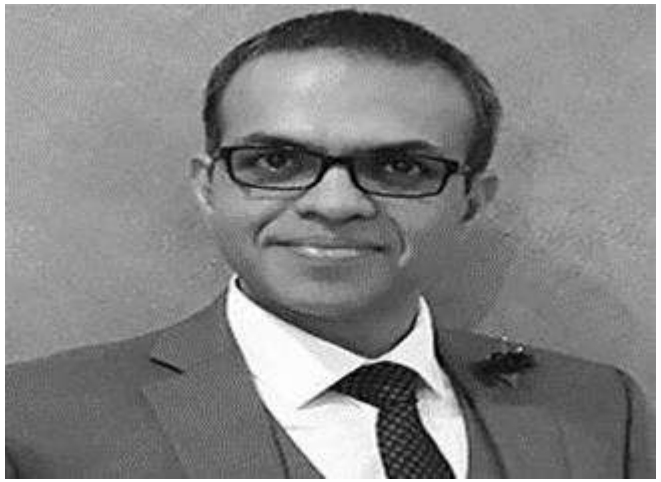
Sachin Tonapi

MBA, CCDM

Sachin Tonapi, MBA, CCDM
Executive Director and Head of India Clinical Data Management
Covance India

- Over 16 years of experience in Clinical Data Management, leading global DM teams serving large, medium, small pharma and biotech companies across different engagement models like FSP, Full Service and Standalone DM services.
- In the current role as Executive Director, Head of Clinical Data Management India at Covance he leads the CDM team in India and also leads the Global Clinical Data Operations Team.
- He is the current Co-Chair for ISCR Council for DM-MW-BIOS
- He is a Certified Clinical Data Manager from SCDM and Certified Six Sigma Green Belt
- He has been associated with industry forums like ISCR, DIA and SCDM

Dr Mukul Manchanda
Deputy General Manager
Medanta Institute of Education & Research



Dr Mukul Manchanda
Deputy General Manager
Medanta Institute of Education & Research

- **Experience - 17 years**
- **Functional Role:** Head – Strategy and Research Operations
- **Work Experience :** Medanta-The Medicity, India
  Cardiovascular Associates, USA
  Heart Specialists, USA

✓ **Accomplishments**

✓Certified Auditor for EC, Site & Pi accreditation
✓Set-up the Clinical Research business unit at Medanta
✓Successfully negotiated over 300 contracts
✓Operationalized over 600 projects
✓Managed team of > 100 professionals across 20 specialties at Sites
✓Setup & Operationalized a Diagnostic Core Lab
✓Analyzed several real-world data sets in NCDs
✓Led a team to configure, train & successfully implement EMR by CSC
✓Data Management procedures successfully implemented for Indigenous & Academic Projects
✓Designed & implemented a Clinical Trial Management System (CTMS)
✓Designed& implemented a digital SAE tracking system, achieving 100% compliance

Ms Meenakshi Kafaltia
Sr. Quality Monitor –Clinical Research, Medanta The Medicity
B.Pharm, PG -Clinical Research

Ms Meenakshi Kafaltia
Sr. Quality Monitor –Clinical Research, Medanta The Medicity
B.Pharm, PG -Clinical Research

Role
•Quality Management System
•Safety Monitoring & Audit
•Training & Education

Work Experience
Medanta-The Medicity, Gurgaon
Apollo Research & Innovation, New Delhi

Accomplishments
✓Instrumental in the creation & setting up of Research Department at Medanta
✓Cross-functional approach: worked in end-to-end clinical trial operations, supervised site regulatory activities & QMS
✓Trained 40 Drug Inspectors on GCP & Site Processes & 5 Drug Inspectors in Mock Inspection
✓Quality Champion -2 international & 3 national accreditation inspections qualified for Research Unit; Successfully managed & cleared 3 regulatory inspections at site
✓Independent reviewer and assessor of Essential Documents, SAEs, Protocol Deviations & Violations for Ethics Committee& Safety Review Committee.

Mr. Kuldeep K. Chauhan

Senior Project Leader-Clinical Trial Operations B.Pharm

Medanta Clinical Research Institute

Mr. Kuldeep K. Chauhan
Senior Project Leader-Clinical Trial Operations B.Pharm
Medanta Clinical Research Institute,

- Masters in Clinical Research Experience – 11 years Expertise :
- Research Operations and Academia
- Role : Project Management Work Experience Medanta Research and Innovation Department , Medanta-The Medicity,
- Duke Medanta Clinical Research Institute, Location India - Gurgoan
- Jubilant Life Sciences , Noida
- Ranbaxy Research Laboratories, Noida
- Clinical Research : Research Operations Area of Expertise
- Project Management – Phase I to IV
- Trial Monitoring
- Supply Chain Management
- Medical Writing and Pharmacovigilance Therapeutic Areas - Rheumatology, Cardiovascular, Oncology & Neurology PK/PD studies
- Contract & budget negotiation
- Business development