Pre-Conference Workshop –
Quality Management and Data Integrity in Clinical Trials and BA/BE studies
– How to be Compliant with USFDA requirements?

23-Jan-2020
Mr. Anirban Roy Chowdhury
Director & Principal Consultant,
ARC LifeScience Consulting Group

- Anirban Roy Chowdhury is a clinical research professional with about 2 decades of experience in the pharmaceutical industry. He started his career as a CRA in AstraZeneca and most recently he was the Executive Director, Global Clinical Trial Operations at MSD (Merck & Co).
- He is the Founder Director and Principal Consultant at ARC Life Science Consulting Group, a boutique clinical research consulting firm.
- He is an Adjunct Visiting Professor at Dept. of Pharmacology, Manipal College of Pharmaceutical Sciences, Manipal.
- Anirban serves in the Executive Committee of the Indian Society for Clinical Research.
Dr. Anil K.
Head – Clinical Research,
SYNGENE INTERNATIONAL LIMITED

- A qualified Medical Professional, with **extensive experience in Clinical Research, Regulatory Affairs, and Quality Management System**, having **19 years** of experience.
- Associated with medical research leaders/pioneers like *Clinigene International Limited, Lotus labs Private Ltd, Mallya Hospital, Bangalore*
- Experience in **Clinical Research** [Phase I to IV trials, BE/BA Studies], **Medical Practice**, and **Quality Management System**
- Initiated and set up Human Pharmacology Units in two organizations.
- Led Phase I & BA/BE Studies, Clinical Trials and Hospital Establishment.
Dr. Chirag Trivedi  
Sr. Director and Head of Clinical Study Unit India and South East Asia Cluster, Sanofi  
President, ISCR

- **Work Experience:**  
  - Currently working in Sanofi as Sr. Director and Head of Clinical Study Unit India and South East Asia Cluster - overseeing clinical studies in India, Singapore, Malaysia, Thailand, Indonesia, Philippines, Bangladesh, Sri Lanka and Vietnam.  
  - Have been with Sanofi since May 2006 and have handled various roles and responsibilities in these years.  
  - Prior to Sanofi, have worked in a CRO and prior to that, in a Central Lab.  
  - Since April 2017, he is the President of Indian Society for Clinical Research (ISCR).  
  - Experienced in the fields of Clinical Research, Clinical Quality Assurance, Medical Excellence, Pharmacovigilance, Bioavailability & Bioequivalence Studies, and Business Development.

- **Educational Qualification:** Ph.D. in Pharmacology

- **Additional information:**  
  - Have been nominated as an external examiner by the University of Mumbai for the Ph.D. (Tech.) and for Masters in Pharmaceutical Sciences Examination (speciality – Pharmacology) for evaluating research thesis.  
  - Have been a Speaker at various national and International conferences
Dr. Partha Gokhale is the Head Clinical Operations- Boehringer Ingelheim India. Partha is a medical doctor and has done his post-graduation in Pharmacology. He is a M.D, D.N.B (Pharmacology) and is also a certified lawyer (L.L.B). During the last 18 yrs, Partha has been involved in increasing responsibilities in clinical research from clinical protocol development, medical monitoring to increasing managerial positions in clinical research. He was instrumental in setting up the clinical research departments of Boehringer Ingelheim India Pvt Ltd and assisted in setting up the clinical research department at Wyeth Pharmaceuticals India. Dr Partha Gokhale is the Chair of the Ethics council of Indian Society For Clinical Research.
Courtney Long is a Bioresearch Specialist with the Office of International Programs- India Office of the US Food and Drug Administration. She performs regulatory inspections of Clinical Investigators, Institutional Review Boards, Sponsors, facilities performing bioequivalence studies, and facilities performing GLP studies. Her inspections cover various product areas including pharmaceuticals, medical devices, and biologics. She previously worked for the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs and has been with FDA since 2002. Ms. Long has conducted inspections in fourteen countries and has worked jointly with regulatory agencies from Europe, Australia, and India. She received her Bachelor of Science Degree in Zoology form Texas A & M University.
Janete F. Guardia
Assistant Country Director, USFDA India Office

- Janete has been conducting bioresearch monitoring (BIMO) inspections in India since 2015 and has been with USFDA since 2009. She holds an MPH in Epidemiology, a Masters in Biomedical Science and a Bachelor’s degree in Biology/Pre-Med. Prior to FDA she worked in private industry as a Research Associate with major chemical, pharmaceutical and food firms.
Dr. Anvita Pandiya
Site Quality Head, Global Development Quality,
Hyderabad, Novartis

- Anvita is a member of the Drug Development leadership team at Novartis India and a member of the Country Quality Board of Novartis in India.

- Prior to joining Novartis, she was a Global GCP auditor at Eli Lilly for the Europe and Asia Pacific region. She has over 25 years of experience including acting as sub-investigator in trials for multiple therapeutic areas, setting up the clinical research unit of Apollo Hospitals Delhi, training investigator sites and ethics committees across India, auditing in over 20 countries and providing quality oversight to all global development functions in India.

- Anvita trained as a physician from Grant Medical College, Mumbai having practiced as an anaesthesiologist and a gynaecologist for over 8 years. She is also a certified six sigma green belt and ISO lead auditor.

- She has been the section editor for the peer reviewed and indexed journal “Perspectives in Clinical Research” and guest faculty for clinical research training institutions like Institute of Clinical Research India (ICRI) and Apollo Hospitals Educational and Research Foundation (AHERF).
Dr. Chirag Desai MD, DM (Oncology)
Consultant Medical Oncologist and Director,
Hemato-Oncology Clinic, Vedanta, Ahmedabad

- Dr. Chirag Desai is a Medical Oncologist of repute and an astute clinical researcher. Before he started his clinical practice in medical oncology in 1999, he was associated with Quintiles as a project manager and then as National Coordinator for oncology trials. He also worked as medical advisor - oncology program from 1999 to 2005.
- He is one of the Founder Directors of Hemato-Oncology Clinic, Ahmedabad.
- Dr. Desai serves as a consultant/Steering committee member/DSMB member for the pharma companies/CROs for early phase as well as phase III clinical trials of NCEs/NBEs, Biosimilars and immuno-oncological drugs.
- He is a member of Tongue cancer and Lung cancer practice guideline subcommittee for Indian Council of Medical Research and of Head and Neck Committee for National Cancer Grid.
- He has been a Principal Investigator in about 40 and co-investigator in about 40 international clinical trials.
- He has about 30 publications in National/International journals to his credit.
- He is a member of Editorial Board of 4 Journals.
- More than 35 MSc (Life Sciences) and M.Pharm students have done their thesis/project under his guidance.