

QUALITY CONTROL AND QUALITY ASSURANCE IN CLINICAL DATA ANALYSIS

Registration – 9:00 AM to 9:30 AM

Curriculum

- What is Quality?
- Quality in Clinical Trials – Regulatory Perspective
- Quality Management System
 - Quality Control (QC) : a strategy of detection
 - Quality Assurance (QA): a strategy of prevention
 - Difference between QC and QA
- Stages of Quality in Design, Conduct and Analysis
- SOPs, Guidelines and Working Instructions on Quality
- Quality Management Plan
 - Stakeholders, Roles and Responsibilities
 - QC Documentation
 - QC Checklist
- Statistics and Programming Activities:
 - Raw Data Evaluation
 - Different deliverables
 - Best Programming Practices
- Ongoing Challenges and Solutions in achieving Quality
- Quality metrics
- Impact of Quality in Business and Patients Life
- Examples & Case studies of common & uncommon Quality Issues
- Open discussion

"Quality is not an act, it is a habit"
– Aristotle

Annual