QUALITY ASSURANCE

“We provide quality as a fundamental principle in all areas of research

Our QA team delivers strategic strength to our operation to ensure any day compliance. QA group strives to keep COD’s head high in the industry via quality by design concept as an enabler.

Our systems are flexible enough to foster continuous improvement and strong enough to ensure quality and compliance

Project Specific Quality Compliance Assessment

Core document review, Vendor Due Diligence, TMF Review, Site Assessments, Pre-Inspection/Audit Preparation

GCP /Compliance Audits

Investigator Site, TMF, Documents, Central, Labs, Effectiveness Audits, & CAPA Process

Pre-Inspection /Audit Preparation

Preparation of Clinical Trial Sites and Other Vendors for Regulatory Inspection or Independent Audits

SOP/WI Development

Develop SOPs, WI, Forms and Templates for various functions of organization to ensure regulatory compliance

Others

- QMS Set up and improvement
- CRO Qualifications
- GAP Analysis
- CSV Audits
- QMS Consulting
- GxP Trainings

QUALITY ASSURANCE

PEOPLE

QA Lead

17 years Experienced Lead Quality Expert Skilled in Clinical Research, Quality Auditing and CRO Management with an experience in setting up GCP compliant clinical research unit & QMS.

QA Auditors

- With 10 years of experience, each SME has in-depth knowledge and domain experience in various phases of Clinical trial.
- Experienced in various clinical trial tools (EDC, rSDV, CTSM, SAS, RAVE, etc.)

CAPABILITIES

- CRO Qualification and Assessments
- Study Monitoring
- Investigative site audits
- Bioanalytical Audits
- Statistical and Data Management Audits
- Regulatory document audits
- Directed/For-cause Audits
- Risk Based/Focused Audits
- TMF Audits
- QMS set up and Improvement
- Gap Identification and Rectification
- Workshop/Training

PERFORMANCE

- Experience of auditing > 1000 GxP audits.
- Over 50 vendor qualification audits including R&D units, Central Labs, Clinical Trial Supply Management, QMS, Clinical EDC tools, etc.
- Over 500 study monitoring & auditing across various Phases of Trial (Healthy and patient population)
- Regulatory experience of over 20 inspections including USFDA, EMA, MHRA, ANVISA, NPRA, WHO, CDSCO, Health Canada and TGA

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