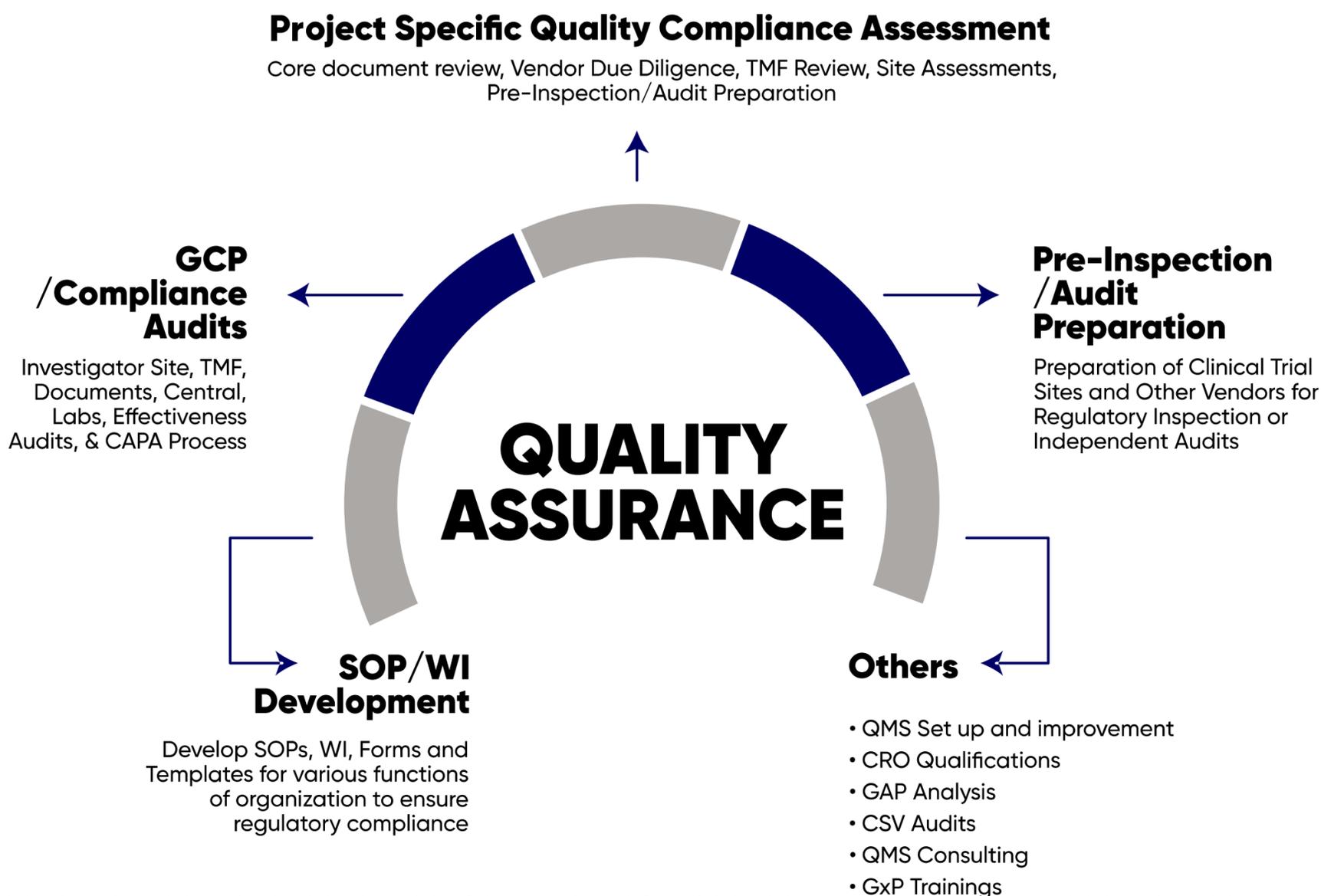




“  
We provide quality as a fundamental principle in all areas of research

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



# QUALITY ASSURANCE



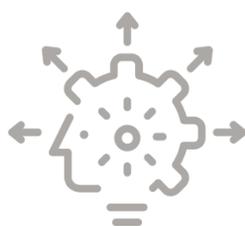
## PEOPLE

### 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



### India Office:

B-3, Salister, B/H Rajpath Club,  
Rangoli Road, S.G. Highway, Bodakdev,  
Ahmedabad – 380054, Gujarat, India

### USA Office:

1011, Route 22, Bridge Water, New  
Jersey -08807, USA

### Contact Us:

+91 79 2960 8246  
bd@cod-research.com