

SERVICES

QUALITY ASSURANCE

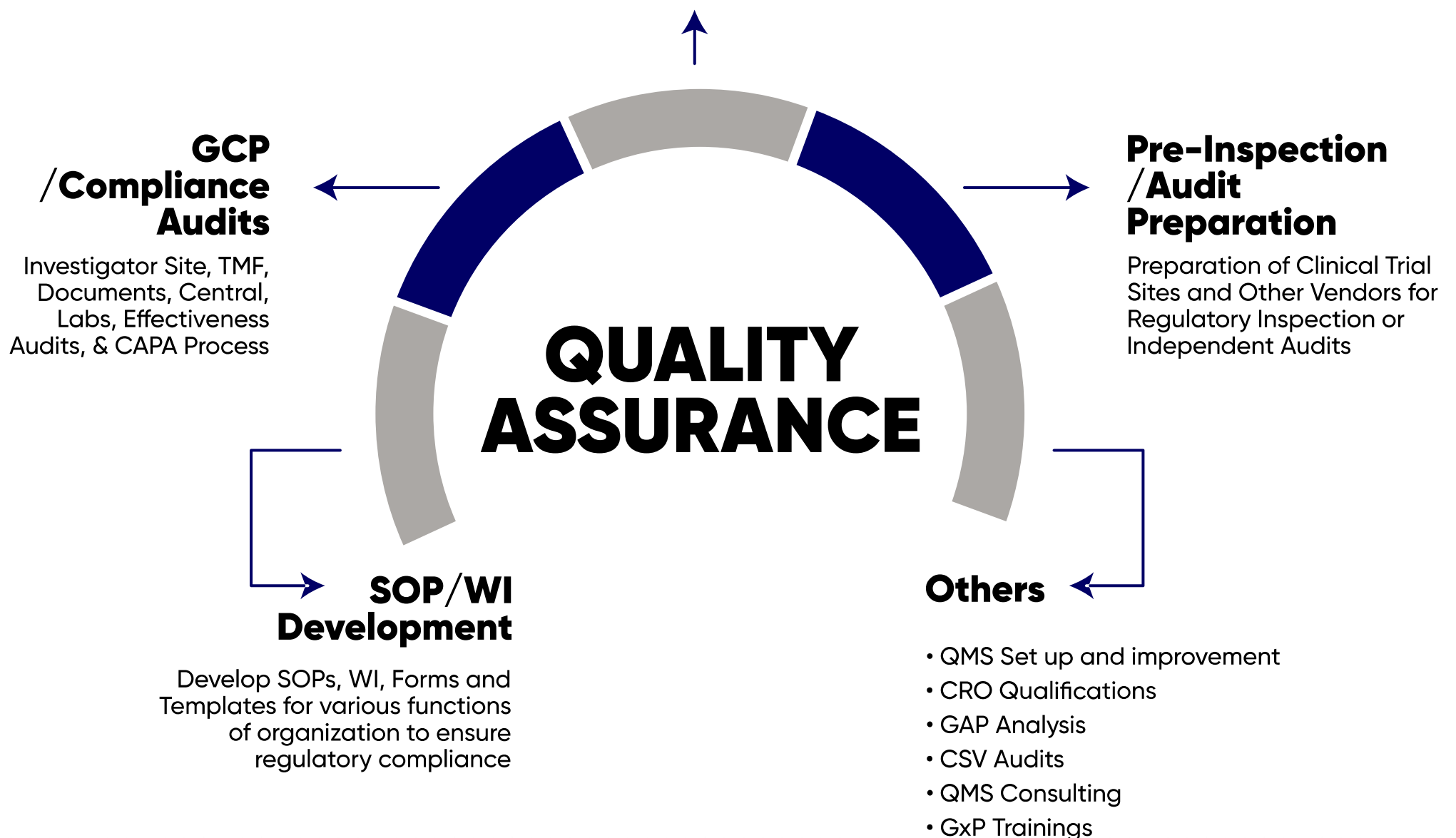
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We provide quality as a fundamental principle in all areas of research

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



QUALITY ASSURANCE



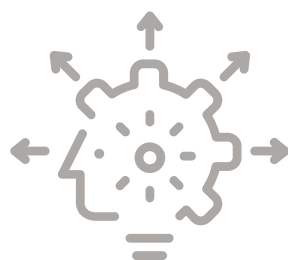
PEOPLE

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