Clinical QA Professional – Home Based, Falcon Consulting Group

Status: Full-time, salary with comprehensive benefits package

Apply: https://falconnest.applicantpool.com/jobs/

This home-based/remote, full time, salaried position is responsible for providing a diverse, high-end range of independent clinical quality auditing services and other clinical research support. Specialized consultancy provided to clients offers unique opportunities for qualified candidates. Overall job responsibilities include but are not limited to global compliance, quality assurance, clinical trial oversight, Investigator and Vendor Audits and Assessments, SOP Gap Analyses and SOP Development, Mock Regulatory Inspections.

Due to home-based/remote, position could be located in any U.S. city.

Primary Responsibilities include:

- Perform domestic (and potentially some international) Investigator Site Audits and a diverse range of Clinical Research Organization (CRO) and Vendor audits in accordance with either Falcon or Sponsor Standard Operating Procedures (SOPs);
- Perform Data , Clinical Study Report, and Regulatory Submission Audits;
- Conduct GCP Training, Inspection Readiness Training and Training on other Clinical Research Compliance topics to Investigators and Sponsors;
- Perform Inspection Readiness Visits to Investigator Sites and Vendors;
- Participate in Mock Regulatory Inspections at Sponsor Facilities;
- Perform Internal Process/System Assessments and Standard Operating Procedure (SOP) Gap Analyses;
- Perform quality control (QC) of documents and data
- Assist and support Senior Director/Director-level Falcon GCP Consultants in the evaluation and development of Sponsor Clinical Quality Systems and Infrastructure.

Position requirements:

Education/Training/Experience:

- Degree in Nursing, Science, or related field (or equivalent);
- Minimum of ten (10) years clinical research and/or R & D experience in pharmaceutical, biotech, medical device and other life science industries;
- Minimum of four (4) years working knowledge and experience in Clinical Quality Assurance
- Prior auditing experience required

Knowledge/Skills/Abilities:

- Strong GCP and Clinical Quality Assurance knowledge, other GXP knowledge a plus
- Aptitude and knowledge to perform independent Investigator Site Audits, CRO/Vendor Audits, and other assignments;
- Experience in performing internal systems assessments and safety/pharmacovigilance audits preferred
- Advanced oral and written communication skills
- Ability to analyze a variety of data points to solve complex problems

- Ability to work independently; planning, organizing, scheduling and completing work within deadlines
- Ability to manage conflicting demands and priorities
- Attention to detail with a high level of accuracy
- Work remotely, within a self-provided designated work space which includes reliable internet connectivity
- Frequent domestic travel with potential for some international travel (total travel 60-70%)

Keywords: GCP, GCP Auditor, GCP Training, CQA, clinical quality assurance, quality assurance, regulatory, clinical research compliance, inspection readiness, pharmaceutical, biotech, medical device, life sciences

Falcon Consulting Group, learn more by visiting: http://falconnest.com

Physical Demands and Working conditions:

While performing the duties of this job, the employee works in an office environment and is occasionally required to stand; walk; sit; use hands to finger, handle, or feel objects, tools or controls; reach with hands and arms; balance; bend; talk or hear. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, depth perception, and the ability to adjust focus.

This position requires regular oral/written interaction with clients, team members and the management team.

Frequent domestic travel with potential for some international travel (total travel 60-70%).

EEO Statement

Schulman provides equal employment opportunity to all individuals regardless of their race, color, creed, religion, gender, age, sexual orientation, national origin, disability, veteran status, or any other characteristic protected by state, federal, or local law. Further, the company takes affirmative action to ensure that applicants are employed and employees are treated during employment without regard to any of these characteristics. Discrimination of any type will not be tolerated.

EEO/M/F/Disabled/Vets

Reasonable accommodation

Reasonable accommodation requests for persons with disabilities may be submitted by email or U.S. Mail. If you require reasonable accommodation during any part of the hiring process, please submit requests to hrteam@sairb.com or mail to:

Schulman Associates Institutional Review Board, Inc.
ATTN: Human Resources Director
4445 Lake Forest Drive, Suite 300
Cincinnati, OH 45242

* Schulman Associates Institutional Review Board, Inc. is the parent company of Falcon Consulting Group