JOB TITLE: Quality Assurance Associate (Part-Time)

ABOUT THE COMPANY

AVIC Solutions is a global leader in Quality Assurance (QA) and Data Privacy compliance, specializing in the clinical trial, pharmaceutical, and biotech industries. For over eight years, we have partnered with organizations to ensure regulatory compliance, mitigate risk, and implement structured quality and data privacy systems aligned with global regulatory frameworks.

Our expertise spans:

- Quality Assurance & Compliance: Development and implementation of Quality Management Systems (QMS) and compliance frameworks aligned with ISO 9001, ISO 27001, ISO 14155, GCP, GMP, and 21 CFR Part 11.
- Data Privacy & GDPR Compliance: Design and execution of comprehensive data privacy programs to comply with GDPR, HIPAA, PIPEDA, and other global regulations.
- Regulatory System Implementation: Establishing and optimizing ISO-compliant governance structures, privacy frameworks, and compliance monitoring systems to ensure organizations meet ongoing regulatory obligations.
- AI Governance: Risk based AI governance and lifecycle controls aligned with the EU AI Act, ISO IEC 42001, NIST AI RMF, and FDA GMLP, including policy and accountability, risk assessment, validation and change control, third party assurance, and ongoing monitoring and incident management.
- We work with pharmaceutical sponsors, CROs, biotech firms, and health technology companies to streamline regulatory processes, ensure data integrity, and maintain compliance with evolving global regulations.

At AVIC Solutions, we are committed to excellence, integrity, and operational efficiency, helping our clients build and maintain structured, sustainable compliance systems that support their long-term success.

POSITION OVERVIEW

We are seeking a detail-oriented and proactive Quality Assurance Associate to join our team on a part-time basis. The ideal candidate will assist with various quality assurance tasks, including document review, report generation, audit agenda generation and review, Gantt chart generation, project management activities, calendar management, and client communications.

KEY RESPONSIBILITIES

- Conduct detailed reviews of controlled quality documents (e.g., SOPs, work instructions, policies) to ensure alignment with applicable regulatory and quality standards; generate review summaries and version control updates.
- Assist in the development and formatting of audit agendas and checklists, and support the drafting and review of internal and external audit reports in accordance with GCP, GMP, and ISO 9001 standards.
- Create and maintain Gantt charts to track project timelines, deliverables, and quality milestones across audits, QMS implementation, and client engagements.
- Coordinate and schedule QA-related meetings, including audit planning sessions, document review checkpoints, and client status updates; ensure timely follow-up on assigned actions.
- Prepare and review client-facing QA communications, including document transmittals, audit notices, follow-up requests, and clarification emails.

- Support the design, documentation, and implementation of Quality Management Systems (QMS), including assisting with procedural development, compliance gap assessments, and QA file organization.
- Collaborate with QA leadership to execute other quality assurance functions as needed, including support for training coordination, issue tracking, and quality metric reporting.

QUALIFICATIONS

Minimum:

- Proficiency in Microsoft Excel and Word.
- Experience with ChatGPT and AI tools for process automation.
- Strong organizational skills and attention to detail.
- Ability to work independently and manage multiple tasks.
- Able to work independently, prioritize tasks, and meet regulatory deadlines
- Familiarity with GxP principles, ISO 9001, and regulatory documentation standards

Preferred:

- Experience in QA, compliance, or regulatory roles in clinical research or pharmaceutical industries.
- Familiarity with project management tools.

EDUCATIONAL REQUIREMENTS

- Bachelor's Degree or higher in Science, Pharmaceutical, English
- 3 years of experience in Quality Assurance in the healthcare or technology sector.

COMPENSATION

- Hourly rate: Commensurate with experience and skills.

APPLY FOR THIS POSITION

All interested applicants are requested to submit a resume and cover letter. We thank all applicants in advance for their interest but only those selected for interview process will be contacted. No third-party recruiters please. AVIC Solutions is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, religion, color, national origin, sex, sexual orientation, gender identity, age, among other things, or status as a qualified individual with a disability.