Quality Auditor I

Position Overview

The Quality Assurance Auditor I is responsible for planning and conducting good clinical practice (GCP) audits, supporting vendor management qualification activities including GxP audits and risk assessment practices, hosting audits by clients, and supporting compliance and quality initiatives.

Primary Responsibilities

To perform this job successfully, incumbent must be able to satisfactorily perform the essential functions of the role without or with reasonable accommodations. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Essential Functions:

- Schedules, plans, and conducts internal process audits according to the Internal Audit Plan and applicable SOP or Work Instruction, including the completion of an audit report. Tracks and manages any post audit activities and follows and corrective or preventative actions to closure.
- Supports the Vendor Management Department through timely evaluation activities, to include the planning and conducting of vendor qualification and re-qualification audits as requested, review of vendor evaluation questionnaires and ongoing monitoring activities.
- Host qualification and For Cause audits of Firma by clients.
- Assists with the coordination of regulatory agency inspections.
- Participates in ongoing audit and inspection readiness activities.
- Identifies non-compliances and may participate in effective Root Cause Analysis and development of corrective and preventative actions.
- May collaborate and serve as a Quality Point of Contact for departmental and cross-functional teams to provide quality support to projects and initiatives.
- May author initial and revised Quality controlled documents, working with cross functional and departmental leads to ensure consistent and applicable processes.
- May author and/or provide training on compliance and quality topics and processes.
- Able to travel up to 20%.

Note: This list is not intended to be an exhaustive list of duties and responsibilities. There may be other duties as assigned.

Qualifications Including Education, Experience, and Skills

- BA/BS degree or equivalent with 3-4 years of quality assurance and GCP auditing experience in the clinical research or healthcare sector
- Excellent verbal and written communication skills and high level of attention to detail
- Strong professional and interpersonal skills
- In depth knowledge of clinical research industry, auditing best practices, and FDA regulations and ICH GCP guidance
- Ability to work independently.

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