

## **Job Posting**

### **Vendor Qualification Specialist**

#### **Position Overview:**

The Vendor Qualification Specialist position will be responsible for the quality related functions associated with Vendor Management. This role will be responsible for the conduct of questionnaire, remote, and onsite Vendor qualifications and audits while supporting the associated administrative functions. In addition, this role will work closely with the Vendor Management and Quality leads to develop and implement new systems and processes in an effort to make efficiencies to current processes while ensuring Firma is meeting its Standard Operating Procedure (SOP) and Good Clinical Practice (GCP) obligations.

#### **Primary Responsibilities and Essential Functions:**

***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.***

- Assess Vendor quality processes via the applicable risk-based audit methodology (questionnaire, remote, or onsite) in order to maintain regulatory and GCP/ICH compliant processes which control the quality of work and clinical trials conducted at Firma.
- For those Vendors requiring remote or onsite audits, responsible for scheduling of audits, developing the audit plan, conduct of the audit, and writing of the audit report. Tracks Vendor Audit Observations information to stakeholders on Vendor status.
- Performs the critical administrative functions necessary to maintain the Vendor Qualification Tracker, Vendor Files and records, and the Approved Vendor List.
- Responsible for reconciling information outstanding and/or overdue for Vendors. Follows-up regularly with Vendors to ensure all qualification items are collected for review and enforces actions to ensure Firma receives the items required.
- Independently manages high volume Vendor qualification activity, whilst respecting urgency of need for Vendor services.
- Develops audit schedules for the coming year and planning/determining need for requalification of current Vendors.
- Works across all functional areas to determine Vendor qualification needs and is able to determine those Vendors' services that may have an impact on subject safety or data integrity.
- Assist in the implementation of and maintenance of the electronic Supplier Management module of the Quality Management System.
- Assists with the coordination of regulatory agency inspections for Vendor oversight functions.

- Participates in ongoing audit and inspection readiness activities related to Vendor Management. May participate in client audits, representing Vendor Management/Vendor Qualification.
- May author initial and revised controlled documents for Vendor Management and oversight 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:**

- Bachelor's Degree or equivalent experience defined as a minimum of 6 years related, combined experience in employment, education, knowledge, and skills that will enable the incumbent to perform the tasks of the role proficiently.
- A minimum of 3 years vendor management experience in the clinical research or healthcare sector.
- Experience with independently performing Vendor qualification including remote and onsite audits.
- Knowledge of the clinical research industry, auditing best practices, and ICH GCP guidance.
- Experience with electronic supplier modules preferred.
- Candidate must be able to work confidently with internal customers of all levels, including Senior Management Level.
- Excellent verbal and written communication skills and high level of attention to detail.
- Strong professional and interpersonal skills.
- Ability to work independently.

*Firma is an Equal Opportunity Employer. Firma does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status, or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.*