Director, GCP and PV Quality Assurance

SUMMARY OF POSITION

The Director, GCP and PV Quality Assurance is responsible for the development and continuous improvement of robust Global Safety and Clinical Quality Management Systems (QMS) for pre- and post-market programs. This position will direct all aspects of Clinical Quality Assurance activities for Good Clinical Practice (GCP), Pharmacovigilance (PV), and Good Vigilance Practices (GVPs). This includes development of strategic audit plans, planning and conducting audits, issuing audit reports, confirming suitability of corrective and preventive actions (CAPA), verifying and tracking CAPAs to completion, and keeping management informed of CAPA metrics. In addition, this role leads or helps prepare Amicus for GCP/PV/GVP regulatory inspections. Other responsibilities include provision of regulatory compliance and QA guidance to clinical and drug safety teams, design and monitoring programs for medical information call centers, reviews and provides QA input into the PV/clinical QMS related policies/procedures and leads training efforts for SOP and regulatory topics in the scope of responsibilities based on needs analysis.

MAJOR ACTIVITIES AND RESPONSIBILITIES

1. Lead and/or Manage Audits (GCP/PV/GVP)
   - Manage and/or participate in complex audits including, but not limited to, internal process audits, internal mock inspections, external vendor audits and clinical investigator site audits; determine compliance status and identify compliance risks
   - Contributes to the strategic development and maintenance of a risk based audit schedule that will effectively monitor Amicus’ compliance with policies/procedures and applicable laws and regulations
   - Evaluates the impact of audit findings and authors (or oversees production of) audit reports, provides guidance on root cause analysis
   - Provides guidance to clinical and drug safety teams on adequate development of corrective and preventative (CAPA) responses, reviews responses for suitability and tracks CAPA commitments to completion
   - Conducts CAPA verification
   - Provides management with updates on CAPA completion status and produces CAPA metrics for Quality oversight committees and senior management
   - Facilitates ongoing quality improvement measures through communication of audit results and compliance guidance/training
2. **Support Pre-and Post-Market Regulatory Inspections**
   - Prepares the Company and clinical sites for regulatory inspections
   - Participates on inspection teams and hosts inspections as necessary
   - Facilitates development of responses to inspection findings, develops and oversees implementation of related CAPA plans
   - Oversees CAPA completion metrics and provide periodic reports to management
   - Conducts or oversees CAPA verification audits and creation of verification binders

3. **General QA duties (including but not limited to)**
   - Author, review and approve GCP/PV/GVP related policies and procedures
   - Lead or support as needed the QA team with regards to SOP and regulatory training needs
   - Quality meetings: Coordinate QA meetings including but not limited to creating agendas, management invitations, collation of slides and generation and distribution of meeting minutes
   - Support the conduct and reporting of GCP non-compliance investigations
   - Support clinical vendor qualification needs as requested
   - Represent QA at Company meetings as needed

**ORGANIZATIONAL STRUCTURE**
The Director, GCP and PV Quality Assurance will report to the Sr. Director Quality Assurance.

**QUALIFICATIONS AND BACKGROUND REQUIREMENTS**

**Educational Requirements**
Minimum of a Bachelor’s Degree or equivalent experience in life sciences, or nursing, or extensive equivalent experience necessary to fulfill position requirements.
- BA/BS degree with 10-12 years experience
- Masters degree with 7-10 years experience
- PhD degree with 5-7 years experience

**Professional Work Experience**
- Minimum of eight (8) years experience in the pharmaceutical/CRO industries, **within Quality Assurance function**
- Must have a solid GCP and/or Drug Safety auditing/inspection experience at a global level. GLP and CFR Part 11 auditing experience preferred but not essential.
Experienced in audit report preparation and managing CAPA development. Vendor qualification and experience with audit of bio analytical labs a plus.

- Experienced in quality metrics creation, reporting and analysis as well as process improvement techniques. Objective writing skills with regards to audit reports, policies and procedures
- Demonstrated knowledge in the regulatory areas of importance to Amicus (e.g., FDA/EU Regulations, 21 CFR Part 11, ICH-GCP, HIPAA/data privacy)
- Strong written and verbal communication, analytical, problem solving and conflict resolution skills. Must be able to communicate professionally at all levels of the organization
- Flexible, highly motivated, with strong organization skills and the ability to multi task. Must be able to manage shifting priorities to meet critical deadlines in a fast paced and dynamic environment.
- Leading a team and development of direct reports is preferred
- Project Management experience preferred
- Experience in managing people and/or working on cross functional teams

**Travel Requirements**
- Ability to travel domestically and internationally up to 25%

**Compensation**
A competitive compensation package will be presented to the right individual including base salary, bonus, and equity.

**Location**
This position will be based at 1 Cedar Brook Drive, Cranbury, NJ, 08512.

**How to apply:**
For immediate consideration, please email your most recent ms-word resume and cover letter to: Careers@amicusrx.com