Apellis

Position: Manager of Quality Assurance in Clinical – GCP

Reports to: Vice President of Regulatory Affairs & QA

Description: The Manager of Quality Assurance in Clinical - GCP will be responsible for managing the efforts of establishing and leading QA function in clinical. The incumbent is responsible for evaluating the compliance and guidelines of clinical studies to FDA and International regulatory agencies during IND, CTA, IMPD, DSUR, PSUR and IB etc. The Manager will also be responsible for identifying and writing of clinical SOPs and training team members. He/She will provide effective oversight of QA systems within clinical and all cross-functional organizations team members involved in clinical research activities. The candidate must have the ability to develop and implement GCP-related quality systems and training of Apelli's staff. He/She will oversee the audit plans and activities and conduct effective audits of investigator sites, documents, Trial Master Files, vendors, and internal and external processes.

Job Responsibilities:

- Plans, conducts, and reports on GCP audits of clinical investigators, vendors, systems plus key reports and documents and facilitates regulatory inspections.
- Prepares and revises GCP SOPs, Work Instructions, creation and maintenance of audit tools, and provides comprehensive internal GCP training programs.
- Participates in cross-functional teams providing guidance and risk based options and represents GCP QA on project teams to initiate, facilitate audit planning both internal and external audits.
- Works with cross-functional teams to provide GCP advice, and supports the internal audit process with regard to documents and compliance and provides guidance on risk- based QA audit options.
- Experience working with clinical trial pharmaceutical regulations and guidance.
- Demonstrates experience conducting detailed internal and external audits of clinical studies, CROs, vendors, with a solid understanding of regulatory inspection processes.
- Reviews clinical study documents and checks for consistency and appropriate standards and practices.
- Participates in cross-functional teams.
- Reviews clinical study documents and checks for consistency and appropriate standards and practices.
- Coordinates projects to successfully meet timelines.
- Additional duties and responsibilities as required.

Experience and Background:

- BA/BS degree or equivalent experience is required; advanced degree in a scientific field preferred.
- At least 3-4 years of experience in clinical Quality Assurance - GCP QA.
- 6 or more years of total biotech/pharmaceutical or related industry experience preferred.

- Broad knowledge of risk-based quality systems approaches consistent with ICH E-6 for Good Clinical Practice (GCP).
- Experience with all phases of clinical trials.
- Strong knowledge of Good Clinical Practices (FDA and ICH), a good understanding of 21CFR Part 11 with respect to clinical processes and systems, including database and eCRF validation procedures, eCTD Quality Assurance, and the ability to identify and/or resolve quality issues/discrepancies with others in a proactive, diplomatic, flexible and constructive manner.
- Experience in leading inspection-readiness activities for FDA and other international regulatory agencies.
- Maintains good working relationships and communication with GCP customers and GxP QA audit staff.
- Understands Clinical SOPs, department controlled documents, GCPs and regulations.
- Knowledge of drug development, study design, data and trials management, procedures, and documentation practices.
- Able to work in a fast paced environment while handling multiple demands and shifting priorities with flexibility and willingness to adapt in a changing environment.
- Excellent communication skills, both verbal and written, strong analytical skills and attention to detail
- Attention to detail as well as a crisp, clear and concise style in written and oral communications.
- Demonstrated ability to flexibly work in a team and independently in a fast-paced, high growth environment.
- Other Requirements include:
    - Strong computer skills, project management skills, and a strong attention to detail, and the ability to manage multiple tasks
    - Experience managing internal personnel and external vendors
    - Extensive experience using electronic document management systems
    - Strong communication skills (both written and oral)
    - Ability to travel both domestic and internationally, as needed
    - Proficient in word processing, spreadsheets and database software applications on a PC, specifically MS Office: Word, Excel and PowerPoint