Job Description

Job Title: Clinical Quality Associate
Department: Quality Assurance
Reports to: Director, Quality and Regulatory Affairs
Work Hours: Full-time
FSLA Status: Exempt

Job Summary:

The Clinical Quality Associate is responsible for managing and ensuring completion and readiness of clinical documentation/master files while overseeing 3rd-party (CRO) conduct of sponsor clinical studies.

Responsibilities:

- Clinical Documentation/Trial Master File (TMF) Management
  - Ensure completion and filing of clinical documentation / TMF by performing quality control (QC) of the TMF and related clinical documentation to ensure completeness, document quality and timeliness of upload of artifacts to the TMF.
  - Collaborate with document authors for review and approval of clinical documentation as needed.
  - Report study status to sponsor team members by providing regular status updates, and facilitating/leading routine TMF meetings and documenting the discussion/decisions.
  - Develop and maintain study-specific TMF structure documentation (i.e., Expected Document List, excel trackers for paper/hybrid TMF).
  - Provide support and prepare TMF(s) for audits/inspections.
- Clinical Procedure Development and Deployment
  - Provide input and communicate sponsor requirements to 3rd-parties related to external clinical procedures, including CROs, clinical project managers and study drug distribution coordinators.
  - Comply with GCP, sponsor SOPs and function area processes.
  - Contribute to improvement/correction/compliance through robust root cause analysis, CAPA implementation/tracking, and reporting/communication of lessons learned to broader organization.
  - Ensure compliance with current global regulatory standards internal standards, processes and procedures.
  - Author and implement changes to internal controlled documents (e.g., SOPs, work instructions, policies) as needed.

- Support of Product Site Quality Assurance Activities
    - Conduct internal and external audits to assess compliance with GMP regulations and company quality standards. Collaborate with cross-functional teams to address and resolve any identified non-conformities.
    - Develop, revise, and implement SOPs and quality policies as needed.
    - Investigate and document deviations, incidents, and customer complaints.
    - Develop and implement corrective and preventive actions to address identified issues.

Required Skills/Abilities:

- A minimum of 2 years of relevant industry experience in clinical document management or equivalent experience.
- Competent knowledge of clinical documentation, clinical operation procedures, regulations and industry standards.
- Effective oral and written communication skills.
- Ability to represent sponsor in cross-functional team meetings and report study status to sponsor team.
- Ability to manage several projects at the same time.
- Prior experience and willingness to learn and support other aspects of quality assurance (i.e. GMP, analytical).

Physical Requirements:

- Prolonged periods of sitting at a desk, working on a computer.

Education:

Bachelor's degree required.

About BioFactura:

BioFactura develops and commercializes biodefense drugs, novel drugs, and high-value biosimilars (i.e., follow-on biologics or generic biopharmaceuticals) using its patented StableFast™ Biomanufacturing Platform, the optimal choice for bringing these products to market with faster, lower cost, superior-quality manufacture. For over 10 years, BioFactura has been advancing life-saving medicines from the research bench to the patient using its innovative drug development and manufacturing technologies. Current and past programs include biodefense drugs against smallpox and Ebola, novel medicines for cancer, and low-cost/high-quality biosimilars for autoimmune and infectious diseases.

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