FHI CLINICAL
Mission-driven clinical research

Regulatory Affairs Officer

Summary of The Position: The Regulatory Affairs Officer will assist the Regulatory Affairs (RA) Team in the execution and coordination of all tasks associated with the regulatory aspects of clinical projects undertaken by the company, in accordance with the relevant trial protocol and other trial-related documentation, ICH GCP, SA GCP (if applicable to geographical area), local regulatory and IEC requirements and local legal requirements and relevant international guidelines in other African countries, the USA (FDA), Europe (EMA), including applicable procedural documents. No direct line management responsibilities but will be required to provide mentorship and training to staff.

Essential Functions:

- Responsible for overseeing and assisting with the collection and collation of all documentation required for regulatory applications to conduct clinical trials.
- Maintain contact with the regulatory authority in South Africa (SAHPRA, Ethics Committees and any other authorities with jurisdiction over clinical trial authorizations, including trial registries, the NHREC, provincial authorities, biosafety directorate, atomic energy board, etc., as applicable to specific trials.
- Similar functions apply to regulatory authorities in other countries, as applicable to specific trials.
- Assist and supervise the coordination, preparation, collection, collation and delivery of all clinical trial correspondence to health authorities, ethics committees and all other governing bodies as applicable.
- Coordinate and/or assist in the maintenance and tracking of documents filed in the TMF (electronic and hard copies) of applicable health authorities and ethics committees according to the project scope of work.
- Coordinate the review of and maintenance of an updated file folder(s) of applicable health authority and ethics committee requirements, guidelines, SOPs, application forms, etc. (reviewed and updated according to company's SOPs and applicable requirements).
- Liaise with the project teams allocated to specific trials, to ensure they obtain all required documentation from the respective sites, in support of regulatory applications and notifications, assuring completeness and accuracy.
- Compile, distribute and file the minutes of project and/or team meetings, as applicable
- Assist in ensuring serious adverse events and safety reports are submitted according to company SOPs and sponsor specifications.
- Train and act as a mentor to RA Assistants (RAAs) for the administrative support associated with the regulatory aspects of clinical projects.

- Perform other ad hoc tasks as required and agreed upon from time to time.

Knowledge, Skills and Abilities:

- Effective oral and written communication skills in English
- Knowledge of other regional languages advantageous
- Thorough knowledge and understanding of the research and development process, all relevant company SOPs, ICH GCP and SA GCP guidelines and other applicable regulations and guidelines
- Excellent interpersonal skills
- Uncompromising attention to detail
- Organization and planning ability
- Computer skills and the ability to learn appropriate software
- The ability to work unsupervised / independently on several projects
- Ability to work independently as well as part of a team
- Ability to mentor less experienced team members in a positive and effective manner

Position Requirements

Education: National Senior Certificate (Grade 12)., Higher Education Training or NVQ Level 5-10., advantageous if in healthcare or science-related field.

Preferred Job-related Experience: Three (3) years' experience and a high level of competency as a Regulatory Affairs Assistant in a clinical research setting