FHI CLINICAL
Mission-driven clinical research

Auditor

Summary of The Position: The Auditor is responsible for planning, conducting, reporting and following up internal and external audits, assessment visits and mock inspections of clinical trial sites and related facilities, in accordance with the applicable audit plans and in compliance with the relevant procedural documents (including but not limited to standard operating procedures [SOPs]) and specifications from ICH GCP, SA GCP, GLP/GCLP, European, FDA and other guidelines and regulations.

Essential Functions:

- Plan, schedule, coordinate and/or perform audit and assessment visits.
- Perform mock inspections as requested by a sponsor or to comply with internal quality management systems.
- Develop and implement audit plans and agendas for audits contracted to the company by sponsors.
- Perform/assist with external/contract audits on behalf of sponsors.
- Plan and conduct internal audits to monitor compliance with SOPs and quality management systems and to identify any deficiencies.
- Document audit observations in an audit report in a clear and objective manner within required timelines.
- Provide suitable recommendations for addressing audit observations, ensuring auditees deliver appropriate corrective and preventive action (CAPA) plans and follow them up through to closure.
- Escalate, as appropriate, where resolution of audit findings is inadequate.
- Assist with the hosting of sponsor audits and provide support for regulatory inspection.

Knowledge, skills, and abilities:

- Expert knowledge of all SOPs, ICH GCP, SA GCP and local legal requirements
- A good working knowledge of GLP/GCLP, European, FDA and other relevant international guidelines and regulations applicable to clinical research
- Proficient medical/therapeutic area knowledge and familiarity with medical terminology
- Effective oral and written communication skills in English
- Strong attention to detail; observational skills; and analytical, inductive and deductive reasoning
- Basic computer skills and the ability to learn and understand relevant software
- Effective organizational and time management, interviewing, probing and negotiating skills

- Ability to work unsupervised/ independently
- Excellent judgment and decision-making skills
- Excellent interpersonal skills and problem-solving ability
- Diplomatic conflict management skills

Position Requirements

Education: Bachelor's or higher graduate degree in a science-related field**,** licensed or certified health care training or equivalent experience

Preferred Job-related Experience: A minimum of five (5) years in a clinical research setting. Audit training and preferably auditing experience