Quality Assurance Auditor

Department	Quality Assurance
Designation	Quality Assurance Auditor
Basic qualification required	Minimum of Bachelor of Arts or Science Degree in a related field or sufficient equivalent relevant training and experience as judged by the site QA management.
Experience	2 - 6 Years
Location	U.S.-Saint Petersburg, FL
Brief JD	• Conduct routine internal audits of projects conducted at the site as scheduled. These audits are intended to assess Cliantha Research site's compliance with Good Regulated Practices (GxP), Quality System Documents (such as SOPs), study protocols, pertinent industry regulations and guidelines; they include, but are not limited to, the following: 1. Pre-study (documentation) audits 2. In-process (procedures and documentation) audits 3. Post-study (documentation) audits 4. Statistics and/or pharmacokinetics 5. Clinical study reports 6. Data management audits 7. CDISC audits 8. Trial Master File audits 9. Validation reports • Review protocols, informed consent forms, source document templates/logs and other project-specific documentation not otherwise reviewed formally in an audit. • Conduct external audits for clinical trial projects to ensure compliance with SOP, Protocol, ICH GCP, quality system and applicable regulatory requirements • Conduct routine process/system audits, as well as audits of validation and/or qualification of computerized systems and facilities. • Conduct qualification audits of 3rd party vendors that provide goods and/or services that support GxP activities at Cliantha Research. • Keep QA Management up to date with findings and follow up on corrective actions. • Perform adequate and timely follow-up of audits, and issue Quality Assurance statements/certificates for

	audits conducted. • Create Quality Plans, Audit Plans or Audit Checklists for assigned projects. • Coordinate with site QA management in the submission and effective maintenance of quality-related data for the development and tracking of quality metrics. • Assist in the hosting of sponsor representatives (monitors, auditors, etc.), IRB personnel and regulatory (e.g. FDA, EMA, HC) inspectors. • Assist the site and QA management in the identification of quality process improvement opportunities and in the development of new processes, documentation and other tools. • Work with the Quality Assurance group in the development/revision and implementation of Standard Operating Procedures as required. • Assist with the archiving of study documents, as needed • Ensure compliance with appropriate Cliantha Research SOP's, GCP (&/or GLP if applicable) and ICH guidelines. • Keep personal training file updated on a regular basis. • Work in a safe manner that does not endanger yourself or co-workers. • Uphold the company mission statement and conduct yourself at all times in a respectful and business-like manner. Be a positive role model for all staff and interact with colleagues in a collaborative way. • Review of SOPS to update the systems in compliance with regulatory requirements • Execute other duties as may be required.

Interested candidates can send their resume at kstowe@cliantha.com