Supervisor Quality Assurance

Department	Quality Assurance
Designation	Supervisor
Basic qualification required	Bachelor in Science
Experience	5-7 Years
Location	St. Petersburg, Florida, USA
Brief JD	**General Responsibilities:** • Responsible for the conduct and oversight of all Quality Assurance activities for all clinical studies in St. Petersburg, Florida, USA • Overall supervision of the Cliantha Research St. Petersburg QA-Team • Schedule QA Auditing Staff to projects to ensure adequate QA support is available as needed • Assistsite QA management in developing the strategies and policies for the QA-Team • Assist site QA management in ensuring that QA staff are trained on required tasks • Train QA Auditing staff on activities as needed • Attend project tracking meetings and provide QA updates on project related activities • Prepare and conduct internal and/or external project audits for clinical trial projects to ensure compliance with SOP, Protocol, ICH GCP, quality system and applicable regulatory requirements. • Prepare and plan conduct of routine process/system audits, as well as audits of validation and/or qualification of computerized systems and facilities • Prepare and plan conduct of 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 audit findings and follow-up on corrective and preventative actions • Analyze and evaluate available data and prepare written Audit Reports of findings and observations to be shared with site and senior management, as required • Prepare and present on a regular basis (monthly/quarterly) quality metrics based on the outcome of Quality Assurance audits • Provide guidance as needed to company staff with respect to ICH and applicable regulations and guidelines • Assist in the hosting of sponsor representatives (monitors, auditors, etc.), IRB personnel and regulatory (e.g. FDA, EMA, HC) inspectors

- Assist the QA management in the identification of quality process improvement opportunities and in the development of new processes, documentation and other tools
- Work with QA management in the development/revision and implementation of Standard Operating Procedures as required
- Ensure compliance with appropriate Cliantha Research SOP's, GCP (&/or GLP if applicable) and ICH guidelines
- Supervise archiving of all study documents internally on a temporary basis and permanently at long-term storage facility and maintaining database of document storage.
- 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
- Execute other duties as may be required

Supervisory Responsibilities:

- Provides work direction and guidance as needed to QA staff

Positions Directly Supervised:

- Site QA staff

Qualifications:

- Minimum of Bachelor of Science Degree in a related field or sufficient equivalent relevant training and experience as judged by the site QA management
- Received industry certification in Quality or Clinical Research (e.g., RQAP-GxP, CQA, CCRC, CCRA, CCRP, etc.) is an asset
- A minimum of five years' experience in a Quality auditing role or equivalent clinical experience in the clinical research industry
- Expert knowledge of, and remaining current with, regulatory requirements pertaining to clinical and/or pre-clinical research (HPFB, FDA, EMA, MHRA, as well as GCP, GxP, etc.)
- Extensive experience in quality review of documents, processes and systems in various phases of clinical trials that will enable only minimal training on the clinical audit program at Cliantha Research
- Attention to detail and the ability to spot inconsistencies is a must
- Executes job responsibilities with very minimal supervision; provides supervision/mentorship to QA staff
- Ability to understand and follow basic scientific research protocol and procedure
- Well-developed analytical and problem solving skills, and have the ability to analyze and interpret scientific data. Proactively identifies problems and helps others with problem solving.
- Decisive, good decision making skills, able to provide leadership to others in response to situations and to escalate more critical decisions when relevant
- Highly effective interpersonal, customer service and conflict resolution skills

	• Advanced proficiency in the use of personal computers and relevant software applications • Excellent organizational skills, detail oriented, efficient and able to multi-task and prioritize effectively • Strong written and verbal communication skills • Excellent interpersonal skills