QA Specialist

Department	Quality Assurance & Regulatory Services
Basic qualification required	B.S.
Location	Mississauga
Experience	2-3 Years
Brief JD	**Job Description / Roles and Responsibilities for Job Title:** **1)** Prepare and 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: **i.** Study authorization to procced – screening & randomization **ii.** Pre-study (documentation) audits **iii.** In-process (procedures and documentation) audits **iv.** Post-study (documentation) audits **v.** Statistics and/or pharmacokinetics **vi.** Clinical study reports **vii.** CDISC audits **viii.** Trial Master File audits **ix.** Validation reports **2)** Review protocols, informed consent forms, source document templates/logs and other project-specific documentation not otherwise reviewed formally in an audit. **3)** Prepare and conduct external audits for clinical trial projects and pharmacovigilance projects to ensure compliance with SOP, Protocol, ICH GCP, quality system and applicable regulatory requirements **4)** Prepare and conduct routine process/system audits, as well as audits of validation and/or qualification of computerized systems and facilities. **5)** Prepare and conduct qualification surveys and/or audits of 3rd party vendors that provide goods and/or services that support GxP activities at Cliantha Research. **6)** Keep QA Management up to date with findings and follow up on corrective actions. **7)** Analyze and evaluate available data and timely prepare written Audit Reports of findings and observations to be shared

	with site and senior management. **8)** Perform adequate and timely follow-up of audits, and issue Quality Assurance statements/certificates for audits conducted. **9)** Create Quality Plans, Audit Plans or Audit Checklists for assigned projects. **10)** Coordinate with site QA management in the submission and effective maintenance of quality-related data for the development and tracking of quality metrics. **11)** Assist in the hosting of sponsor representatives (monitors, auditors, etc.), IRB personnel and regulatory (e.g. FDA, EMA, HC) inspectors. **12)** 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. **13)** Work with the Quality Assurance group in the development/revision and implementation of Standard Operating Procedures as required. **14)** Assist with the archiving of study documents, as needed **15)** Ensure compliance with appropriate Cliantha Research SOP's, GCP (&/or GLP if applicable) and ICH guidelines. **16)** Keep personal training file updated on a regular basis. **17)** Work in a safe manner that does not endanger yourself or co-workers. **18)** 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. **19)** Execute other duties as may be required. ***Any Additional responsibility given by Head of the Department / Management*** **Qualifications:** • 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. • 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 (QC/audit) of documents, processes and systems in various phases of clinical/pre-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 a must. • Executes job responsibilities with very minimal supervision; instead, provides some degree of supervision/mentorship to other 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

Interested candidates can send their resume at **shmishra@cliantha.com**