Job Description

Designation/Role: QC Specialist, Level 1

Department: Clinical Operations

Job Description / Roles and Responsibilities for Job Title:

1) Handles tasks under direction and guidance
2) Perform quality control procedures for clinical trials managed by the Clinical Operations department; review all study documentation for accuracy, consistency and completeness
3) Work with QC manager, Clinical Operations management and study management staff to create study specific QC plans that outline the scope of quality control procedures to be followed during clinical trials, ensuring QC processes are in alignment with Cliantha Research SOPs and study protocols
4) Work with the QC manager to schedule live and post-visit QC activities to ensure that all requirements of the QC plan are executed
5) Assist with the development of; and utilize QC checklists and other QC tools designed to document/track the QC review process
6) Communicate findings from QC reviews to the appropriate Clinical Operations staff via QC summaries, reports or verbally as required.
7) With some guidance, follow-up on all QC findings, as required, until a satisfactory resolution has been determined
8) Assure documentation review meets or exceeds designated timeline parameters
9) Maintain a working knowledge of relevant US, Canadian and European GxP regulations as well as ICH regulations
10) Ensuring training file and SOP reading is maintained and up to date
11) Actively participates and assists in all team study activities and conduct with a willingness to learn
12) Ensure compliance with appropriate Cliantha Research SOP's, GCP and ICH guidelines
13) Participate in training sessions
14) Participate in training of staff as experience and qualifications permit
15) Work in a safe manner that does not endanger yourself or co-workers
16) Execute other duties as may be required by the QC Manager and other members of Management team as training and experience allow

Any Additional responsibility given by Head of the Department / Management

Qualifications:

- High School diploma or equivalent. Prefer a Bachelor degree, with a minimum of two years of college, university, or technical school education in life science or relevant scientific discipline.
- Ability to use computers and software associated with their job function (e.g. Microsoft Excel, Word and Outlook)
- 0-2 years of relevant experience in a clinical research setting

- Strong eye for detail and ability to spot inconsistencies a must
- Good conflict management skills
- Displays a basic ability to identify, anticipate and define issues in a timely manner and to understand the potential impact of issues. Sufficient awareness to notify a supervisor when the problem is beyond the individual's ability to resolve, or as otherwise appropriate.
- Displays some analytical and problem solving skills and the ability to present solutions
- Excellent organizational skills, detail oriented, efficient and able to multi-task and prioritize effectively
- Excellent interpersonal skills
- Strong written and verbal communication skills

The resumes can be submitted to HRMississauga@cliantha.com