Qbtech

Clinical Research Manager

Job Title: Clinical Research Manager

Department: Medical and Regulatory Affairs Department

Reports To: Head of Clinical Research

Summary of Position
Responsible, as delegated by the Head of Clinical Research, for the initiation, administration, monitoring and reporting of collaborative and pivotal clinical studies. This includes tasks such as: Writing synopses, protocols, and ethical review board submissions. Secure timely inclusion of patients/subjects in the studies and keep relevant forms updated. Perform monitoring visits when necessary at sites. Comment on manuscripts with focus on securing adequate information about our products and assist in writing manuscripts for internal studies. Highlight published material to Qbtech employees and update the publication list. Assist in Regulatory Affairs projects (i.e. secure that Qbtech follows relevant regulatory guidelines). Special emphasis for this position involves effective data management by use of Excel and SPSS.

Essential Duties and Responsibilities

- Secure that contracts are prepared and signed.
- Writing protocols and ethical review board submissions for internal studies.
- Secure that inclusion of patients/subjects follow schedule and keep relevant forms updated.
- Regular communication with research sites, including conducting onsite monitoring visits when necessary.
- Comment on manuscripts with focus on securing adequate information about our products. This includes involvement in writing manuscripts for internal studies.
- Highlight published material to Qbtech employees and update the publication list.
- As delegated by the Head of Clinical Research, be responsible for certain pivotal internal research development projects involving validation of significant changes of current products or validation of new products under development.
- Responsible for retrieving and performing quality control of data files for clinical studies.
- Give feedback to researchers, in cooperation with the Clinical Advisors.
- Assist research collaborators with statistical reports.
- Together with the Head of Clinical Research, improve the quality of data such as the automated warnings in the data extractions and improve outputs from the report generator.
- Together with the Head of Clinical Research and Medical Director, secure an efficient system for data filing with special focus on data-files on internal study data yielding clear audit trails.
- Assist the Head of Clinical Research and the Medical Director in securing that slides, websites and other written material have sufficient scientific quality and follow Qbtech's policy for medical/legal adequacy.

- Assist the Head of Clinical Research and the Medical Director in Regulatory Affairs projects (i.e. secure that Qbtech follows relevant regulatory guidelines).

Supervisory Responsibilities

- None

Authorities for Position

- Authorized to perform quality control of study data outputs in Excel and SPSS.
- Authorized to encrypt and deliver internal restrictive data (such as patient data) to customers with an approved and valid research agreement or customers with a commercial contract that has, in writing, asked Qbtech to provide them with this data.

Competency Required for Position

- Strong written and verbal communication
- Experience with or knowledge of the diagnosis of ADHD, including but not limited to, knowledge of DSM-5 diagnostic criteria and relevant professional standards.
- Consistent knowledge of new research, studies, and updates in ADHD.
- Understand the implications of working in a regulatory environment.
- Be trained in all processes and procedures in the Quality Management System (ISO 13485 and ISO 27001) that relate to this position.
- Strong presentation and training skills including adaptability to various professional environments and audiences
- Strong skills in data management issues with specific reference to SPSS and Excel applications
- Basic understanding of statistical methods used when analyzing scientific data.

Qualifications Required for Position

- Master's degree or higher in the field of Research, Mental or Behavioral Health
- One-year of clinical experience in diagnosis and assessment of mental health conditions preferred
- Experience administering neuropsychological tests preferred
- Previous publication experience within behavioral and/or neurological disorders at Master's or PhD level
- 2 years of experience in human subjects research
- Legally eligible to work in the United States
- Valid Driver's License
- Ability to pass background check

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Work Environment
This position is office-based in Houston, TX. Occasional travel domestically and internationally COVID-19 work environment: Position will be working remotely through Spring 2021 therefore professional home office environment is required.