Visionary science for life changing cures.

Clinical Trial Manager

AGTC is seeking a highly motivated individual to coordinate all clinical trial activities and provide support for submission of documents to regulatory agencies.

Reporting Relationship

- The Clinical Trial Manager reports to the Vice President of Clinical Research and Development.

Responsibilities

Job responsibilities will include, but are not limited to, the following.

- Manage clinical trials including investigator selection, analysis of potential patient recruitment, closely track enrollment, preparation of trial-related documentation (protocols, case report forms, investigators brochures, consent documents, letters of agreement, confidentiality agreements), and interactions with clinical sites to ensure successful outcomes.
- Manage Contract Research Organizations (CRO), including initial identification of suitable partners, defining CRO responsibilities, communication plan development, division of responsibilities, managing milestones, contracting with CRO, reviewing monthly status reports, and providing interactive management of CRO to ensure project success.
- Manage patient recruitment strategies to ensure efficient enrollment into clinical trials.
- Work with Clinical R&D and vendors to develop eCRFs, conduct test runs, develop edit checks, ensure appropriate data is being entered; track queries during study and assist with resolution.
- Maintain project files including all regulatory documents, e.g., IRB and ethics committee approvals, curricula vitae of investigators and study personnel, clinical investigators brochure, protocols, case report forms instructions, informed consent documents, clinical trial material shipping orders, start-up meeting attendance documentation, letters of agreement, lab reference ranges, all investigator and site correspondence, schedules of payment, and all other study-related documents.
- Manage clinical trial materials to ensure product is available at clinical sites, correctly stored and administered, and appropriate records are maintained.
- Assist with regulatory filings, including drafting, editing and preparation of routine correspondence and sections of INDs, BLAs, NDAs, Annual Reports, Amendments, Supplements, Orphan Drug Applications, and other regulatory submissions.

Requirements

The successful candidate will meet the following requirements.

- B.S. and/or M.S. degree in a scientific discipline and at least 8 years of clinical research experience with an in-depth understanding of GCP and FDA IND regulations.
- Experience working with biotechnology products preferred.

AGTC offers a competitive compensation commensurate with education and experience. AGTC is an EOE and maintains a drug free workplace. Please send CV or resume to:

Human Resources
Applied Genetic Technologies Corporation
14193 NW 119th Terrace, Suite 10, Alachua, FL 32615
jobs@agtc.com