

Job Description: Clinical Trial Manager

COMPANY DESCRIPTION

Gravitas Medical is revolutionizing enteral feeding with smart feeding tubes, monitors, and pumps. See <https://www.gravitasmedinc.com/> for more information.

POSITION DESCRIPTION

The Clinical Trial Manager will be the **clinical leader** for Gravitas clinical research studies and products and will make clinical research strategy recommendations. This role manages investigative sites, including interviewing/screening investigators and monitoring/auditing regulatory documents to ensure compliance with company SOPs, GCPs, and applicable regulatory requirements. The role also spearheads the hiring, training, and managing of CRAs and identify and manage CROs, vendors and consultants.

ESSENTIAL FUNCTIONS

- Writes and reviews clinical protocols and provides input from an operational perspective.
- Drives the identification, assessment and management/oversight of contracts, CROs, vendors, EDC decisions and implementation, and program-related consultants. Facilitates development of and reviews study-related documents, including informed consent forms, case report forms, clinical study reports, and departmental SOPs.
- Identifies and evaluates investigators.
- Finalizes training materials and leads investigator and study staff training.
- Manages subject enrollment, adherence to inclusion and exclusion and ensures sites are following protocol procedures.
- Manages and conducts monitoring/co-monitoring investigative sites and CRFs to ensure data quality and integrity.
- Manages clinical study protocol(s)/program(s), including the review and approval of monitoring reports.
- Processes for review and approval informed consent documents.
- Conducts ongoing review of regulatory document files.
- Monitors/co-monitors and/or audits clinical studies to ensure data quality and integrity.
- Ensures adequate investigational clinical trial supplies and devices are maintained at the site.
- Manages and reports study site and overall program progress.

Berkeley, CA

- Respond to audits conducted at selected study sites.
- Conducts the selection, hiring, training, and supervision of CRAs, as necessary.
- Leads review/execution of Clinical Trial Agreements.
- Assists President/CEO in short/long term planning.
- Organizes and participates in study team and investigator meetings.
- Responsible for device accountability
- Ensures SOPs are followed and current.
- Thorough understanding of GCP

REQUIREMENTS

- Minimum of a bachelor's degree
- Minimum of 8-12 years medical device or pharmaceutical industry clinical research or clinical research site-based experience. Any equivalent combination of education, training, and/or experience that fulfills the requirements of the position will be considered.
- Startup experience preferred

To apply, please send your resume to hr@gravitasmedinc.com