Clinical Operations Manager — Joint Purification Systems, Inc.

Description:

Joint Purification Systems is a clinical stage company with a high energy team commercializing innovative technology to treat infected joint replacements (hip/knee). The Clinical Operations Manager is primarily responsible for ensuring that the assigned clinical trials are executed in accordance with the protocol, all applicable regulatory guidelines and in a manner that will best support an accurate and compelling clinical study report at the conclusion of each trial. This is a hands-on position responsible for successful execution of the clinical trial. Significant travel and interaction with site personnel on an ongoing basis is required. The COM is a critical team member, reporting to the CEO and may also be assigned tasks by the Clinical Affairs Director.

Principal Responsibilities:

- Provide efficient day-to-day management of the Phase 3 clinical trials for combination drug and device product to treat PJI
- In collaboration with the Clinical Affairs Director, provide clinical site support for JPS products, protocols and related study documents in person and in writing to all stakeholders
- Create and maintain the monitoring plan and manage contracted Clinical Trial Monitors activities
- Interface with investigators, clients and other study stakeholders to facilitate study execution
- Advise and assist in preparation of new study protocols, budget and strategic planning
- Attend scheduled study procedures as directed
- Lead activities related to IRB submissions, site initiation and closeout
- Lead the delivery and maintenance of site level JPS product training
- Identify, resolve or escalate critical issues in timely manner

The Clinical Operations Manager role requires building and maintaining professional relationships with a wide range of clinical investigators, site personnel and contractors. The COM is primarily responsible for tasks associated with executing the clinical trial including site training, maintenance of the TMF and Study/Patient binders, protocol CRF and IC modifications, IRB submissions, AE and deviation documentation and data monitoring. The position requires approximately 75% travel to clinical study sites during patient enrollment and treatment.

Education and Experience

- At least 3 years' experience as a Clinical Trial Manager or Clinical Project Manager
- Pharmaceutical product experience required, medical device experience preferred
- Successful completion of an accredited BA/BS program
- CCRC Certification, or similar
- Prior experience as a CRA and the ability to monitor sites is required

Skills and Competencies

- Effective verbal and written communication skills
- Ability to communicate at multiple levels of an organization and with clients
- PC skills to include: MS Office and electronic data capture systems
- Ability to organize and manage multiple priorities
- Ability to generate and maintain accurate records

Location

Solana Beach, CA