Title: Clinical Project Coordinator

The Company:

Flexion Therapeutics is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis (OA), a type of degenerative arthritis. The company is currently advancing a drug candidate that has the potential to provide rapid, powerful, and durable pain relief compared with existing therapies.

Our lead product candidate, Zilretta™ (also known as FX006) is a sustained-release, intra-articular, non-opioid investigational treatment in late-stage development for patients with moderate to severe OA pain.

The Role:

The Clinical Project Coordinator (CPC) will be responsible for providing administrative and operational support for all aspects of a clinical study in accordance with applicable policies and procedures. Track and communicate overall study status by generating meeting agendas, minutes, trackers, and status reports; and distributing to internal and external parties, as appropriate.

Responsibilities:

- Provide general assistance and administrative support to the Clinical Project Teams
- Ensure trial master files are current and maintained per any relevant SOPs
- Process site payments. Track payments against contract and budget projections with input from the CPM or senior level staff.
- Coordinate site contracts from review through execution
- Maintain contact with investigative sites for specific requests, for example, obtaining regulatory documents (1572’s, CV, etc.)
- Assist with tracking and qualify investigators (e.g. investigator database, feasibility)
- Review site essential documents for completeness (under the direction of the CPM or senior level staff)
- Coordinate study document translation, if required
- Assemble study manuals, binders, presentations and tools, under the direction of the CPM or senior level staff.
- Attend project team meetings and generate meeting minutes
- Coordinate study supplies
- Distribute key study documents and communication to appropriate internal departments and external stake holders (site, vendor etc.) under the direction of the CPM and senior level staff.

Requirements:

Experience Required:

- Working knowledge of GCP, ICH and relevant CFRs is required; familiarity with EMA/CHMP regulations and guidelines and other international regulatory requirements is a plus
- Strong organizational skills, with keen attention to detail and ability to prioritize multiple assignments in a fast-paced environment
- Excellent communication, writing and presentation skills; must be highly computer effective
- Demonstrated ability to form strong functional relationships, maintain a positive attitude, and ability to interact with all levels of staff to coordinate and execute study activities

Education:

Requires a BA/BS, RN, or related degree with 1 to 2 years of relevant experience in CRO or Sponsor setting

To apply for this position, please send your resume as an attachment to:

work@flexiontherapeutics.com