Title: Sr. Manager/Associate Director
Pharmacovigilance Operations

The Company:

Flexion Therapeutics (NASDAQ: FLXN) is a specialty pharmaceutical company focused on the development and commercialization of novel non-opioid pain therapies. The company is currently advancing a portfolio of injectable drug candidates that have the potential to provide better and more persistent analgesia compared with existing therapies.

The company’s lead program, FX006, is an intra-articular sustained release steroid injectable in Phase 3 development for patients with moderate to severe osteoarthritis (OA) pain. We also have two additional product candidates: FX007, a locally administered TrkA receptor antagonist for post-operative pain, and FX005, an intra-articular, sustained-release p38 MAP kinase inhibitor for end-stage OA patients.

Flexion is based in Burlington, Massachusetts.

The Role:

We are looking for a knowledgeable Sr. Manager/Associate Director of Pharmacovigilance Operations to join our growing team. This is a fabulous opportunity to impact the organization and its goals by optimizing Flexion’s drug safety operations. By working with internal departments and external partners and CROs you will have visibility and an opportunity to develop and grow critical relationships to Flexion.

Flexion announced in February positive data from its Phase 3 study of FX006 (Zilretta). As we continue our growth during this critical period, your role will ensure uninterrupted, cost effective movement and delivery of goods throughout the Supply Chain.

Osteoarthritis is a painful and debilitating musculoskeletal disease and the incidence is increasing rapidly, expected to affect 45 million Americans by 2030. Current treatment options — including opioids and common anti-inflammatory medicines — are not always effective, and many carry serious risks and side effects. We are excited to build a team that can make a difference for patients and their families.
Responsibilities:

- Oversees PV activities including vendor oversight for all Flexion clinical trials.
- Ensures that performed tasks comply with DS and PV SOPs and policies, best industry standards and applicable regulations. Monitors compliance with regulations, PV agreements and internal SOPs.
- Ensures seamless and compliant Safety Data Exchange with all Flexion PV Partners and third parties.
- Ensures adequate adverse event collection in all clinical development and post approval medical research.
- Processes adverse events including case triage, data entry, coding review and narrative writing.
- Provides safety operations support for external submissions, signal detection and risk management planning activities.
- Participates in authoring of periodic safety reports (e.g., DSUR, PSUR)
- Works with QA department to maintain a state of high PV inspection readiness across all regions/countries.
- Collaborates with contract service providers for case processing, aggregate reporting and quality management activities.
- Performance management of PV systems.
- Ensures that drug safety operations in clinical development programs and post marketing are aligned with policies and procedures as well as agreements and conventions.
- Ensures that the PV procedures meet best industry standards of efficiency and compliance.
- Oversees the exchange of safety data between functional groups within and outside of Flexion.
- Provides training to Flexion representatives on their safety reporting responsibilities.
- Represents Drug Safety and Pharmacovigilance on clinical development teams, as assigned.

Requirements:

- BS in a Life Science degree is required. Clinical degree (Pharm. D., RN, RPh.) is strongly preferred.
- At least 5-8 years of direct Pharmacovigilance operations experience is required.
- Minimum of 2 years of experience working with CROs, vendors, and relationship management preferred.
- Strong knowledge of safety database, MedDRA coding and data entry experience.
- Strong quality focus, with a good understanding of quality systems.
- Solid knowledge of FDA, EMA, and ICH safety reporting regulations and GVP guidelines.
- Excellent communicator, both oral and written, specifically medical writing skills.