

Company:	Brogan Pharmaceuticals	Location:	US-IN-Crown Point
Status:	Full Time, Employee	Job Category:	Biotechnology and Pharmaceutical
Relevant Work Experience:	7+ to 10 Years	Career Level:	Project Manager Clinical Affairs (Manager/Supervisor of Staff)
Education Level:	Bachelor's Degree	Aseptic Processing	Parenteral Products

Job Description

The position requires an exceptional candidate with the ability to multitask within various clinical development protocols and projects across a variety of disease states. The position will require the management of a variety of projects, CRO selection, management, and audits with varying degrees of oversight to ensure meeting objectives. The team member will participate on multitasking technical teams, building upon and improving existing clinical processes, designs, and optimizing processes for current and future clinical development pathways, manages contract research opportunities, preclinical SBIR/STTR collaborations, and directs outsourced vendor relationships. The position has the opportunity to develop and advance through various management and executive level positions.

Job Responsibilities

- Provides clinical research program management for the Clinical Affairs and Medical Affairs departments.
- Authors clinical studies protocols and supporting documents (informed consent, investigators and IRB approval contracts) for both human and animal studies.
- Monitors accurate, complete and timely data submission by clinical investigators, and implements corrective action as necessary.
- Generates clinical data reports, supports interim monitoring and pre-market approval applications (PMAA).
- Authors clinical section text of PMAAs.
- Manages and provides work direction to Clinical Affairs department staff.
- Functions as the principal physician/AMS interface for clinical research projects as assigned.
- Provides support to Marketing departments by provision of clinical expertise for sales force information, promotional literature creation, marketing plans, sales strategies and product labeling as needed.
- Assists in contract negotiations with outside professional services as directed; integrates such services with capabilities of AMS staff for specific clinical projects.
- Drafts and administers investigator compensation programs.
- Supports investigators wishing to publish, or present orally, products under clinical investigation.
- Assists Regulatory department with reporting any unanticipated adverse events.
- Assists AMS Quality department in processing Field Experience Reports (FERs) and Medical Device Reports (MDRs) to FDA, as necessary.
- Recruits, selects and trains clinical investigators in protocol and data submission requirements.
- Supervises the design and administration of computerized databases.
- Maintains contact with hospital IRBs as necessary to secure institutions as clinical study centers.
- Develops strategic plans for department, Formulates department budget and manages expenses to approved budget.

QUALIFICATIONS / EDUCATION

- Has working knowledge of IDE, PMAA, GLP, GCP, 510(k) and reimbursement processes. Six Sigma
- BS in Biometry, Epidemiology, or medical/clinical sciences (e.g., Physiology, Nursing, Pharmacy, MD)
- Seven or more years related experience in drug, medical device or epidemiological multi-center studies
- Two to five years managing a clinical research department, or equivalent management/supervisory
- Strong knowledge of Federal Food, Drug and Cosmetic Act (FD&C Act)
- Strong knowledge of regulatory principles, especially relating to pharmaceutical development