

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 Regulatory Affairs (Manager/Supervisor of Staff)
Education Level:	Bachelor's Degree	Aseptic Processing	Parenteral Products

Job Description

Your responsibilities will offer you the ability to guide, direct and charge commercialization activities by integrating with product development, R&D, marketing, medical affairs, legal, regulatory compliance and senior management. The position will require an exceptional candidate with the ability to transcend customary corporate boundaries. This is highly visible and integrated position offering unprecedented opportunity to work throughout the organization on a variety of projects. You will contribute to multitasking technical teams, building upon and improving existing processes, designs, and optimizing processes for future FDA submissions, contract manufacturing opportunities, outsourced vendor relationships and operations at the firm’s FDA registered manufacturing facility.

Job Responsibilities / Activities:

- Interpret directives, regulations and guidelines.
- Develop and implement strategies for electronic submissions.
- Assist in the development and execution of global regulatory plans.
- Regulatory document generation including pre-IND/IDE briefing documents, INDs, IDEs End-of-Phase II briefing documents, CMC, clinical study reports, NDAs and PMAs (including Integrated Efficacy and Safety Summary documents).
- Interact with senior level management concerning significant regulatory matters to obtain services to support regulatory objectives.
- Represent regulatory affairs to other departments and provide guidance on adherence to regulatory guidelines for effective submissions.
Maintain policies to assure adherence to and compliance with all applicable FDA/ICH guidelines and with current GLP, GMP and GCP guidelines.
- Analyze trends and evaluate impact of government regulatory activities.
- Build excellent relationships within and outside the Company, as appropriate.
- Create and revise SOPs governing Regulatory Operations activities.

The foregoing job description is not all-inclusive of the duties to which the employee may be assigned. In order to maximize flexibility and efficiency, and to promote and encourage crosstraining, employees will be assigned to additional duties as are deemed necessary or desirable for future advancement within management.

Requirements

- Bachelor’s Degree or higher
- Experience in pharmaceutical quality assurance, quality control and regulatory affairs
- Strong knowledge of Federal Food, Drug and Cosmetic Act (FD&C Act)
- Strong knowledge of regulatory principles, especially relating to pharmaceutical development

Brogan Pharmaceuticals is dedicated to the achievement of equality of opportunity for all its employees and applicants for employment without regard to race, color, religion, sex, gender identity, sexual orientation, marital status, age, national origin, disability, veteran status or any other protected group status under federal, state or local law.