Manager/Senior Manager, Clinical Regulatory Affairs

Reports to: Director of Clinical Regulatory Affairs

Classification: Exempt

Summary:
The Manager/Senior Manager Clinical Regulatory Affairs role is hands-on and will contribute to the initiation and maintenance of global Phase 3 clinical trials. This position will provide direct support to US regulatory submissions as well as the overall global regulatory strategy. The position will work closely with the clinical development team and external consultants to ensure Regulatory submission success including participating in the planning and submission of CymaBay Therapeutics first new drug application (NDA). This individual is highly-collaborative, creative, flexible to different ideas, and can remain grounded in a dynamic fast paced environment. Of importance, is this individual's willingness to assist others when called upon to ensure the success of the team and business objectives.

Essential Functions and Job Responsibilities:

- Manage the preparation, review and assembly of regulatory submissions and oversee the maintenance of regulatory filings to support global clinical trials (i.e., initial INDs, CTAs, amendments, safety updates, and annual reports)
- Critically review and provide comments on clinical trial related documents including clinical protocols, informed consent forms and investigator brochures
- Ensure regulatory submissions are of high quality and submitted in a timely manner; review submissions for accuracy, completeness, and compliance with applicable regulatory requirements and procedures
- Review and approve investigator packages to enable drug shipment to clinical investigative sites
- Organize and maintain regulatory submissions and regulatory information trackers for assigned programs
- Coordinate regulatory workflow with regulatory operations department, and assist in the final submission QC
- Manage regulatory communications, including drafting of letters based on templates
- Provide advice and guidance to project teams on the interpretation and application of relevant regulatory requirements and applicable guidance documents
- Complete other responsibilities as assigned and agreed upon

Minimum Qualifications:

- Bachelor's degree or equivalent education and at least 5 years of relevant experience in Regulatory Affairs
- Experience in preparing IND, CTAs, NDAs and BLAs
- Knowledgeable of GCP requirements and FDA guidelines
- Excellent writing and organizational skills, and an ability to generate clear, concise documents
- Proficiency using Microsoft Word, Excel and PowerPoint
- Strong organizational skills, communication and interpersonal skills, and attention to detail
- Demonstrate ability to manage priorities, multi-task and follow projects through to completion