Regulatory Affairs Specialist

Reports to: Director of Clinical Regulatory Affairs

Classification: Exempt

Summary:
The Regulatory Affairs Specialist reports to the Director of Clinical Regulatory Affairs. The role will support submission activities to maintain Investigational New Drug Applications (IND) in accordance with the Code of Federal Regulations (CFR), support the initiation and maintenance of Clinical Trial Applications (CTAs), and support the clinical activities associated with New Drug Application (NDA) filings. This position will work closely with the clinical development team and external consultants.

Essential Functions and Job Responsibilities:

- Assist with the preparation and QC of Module 1 or other reports/documents that support or are included in the NDA
- Review and approve investigator packages to enable drug shipment to clinical investigative sites and coordinate the monthly investigator IND submission with regulatory operations
- Organize and maintain regulatory information trackers for assigned programs
- Create and maintain an Investigator FDA 1572 tracker
- On a routine basis, this position will gather information for the assembly and review of routine IND submissions including but not limited to IND amendments and annual reports (DSUR)
- Review and QC clinical documents including protocols, clinical study reports, investigator brochure, and other documents for consistency and accuracy
- Review informed consent forms (ICF) against the ICF checklist and ensure the required elements are described
- Ensure that the components of the CTAs are complete and that the content of the associated forms is accurate
- Work with clinical operations to ensure that the Transfer of Obligations form is completed for each clinical study and in accordance with the CymaBay process
- Perform other related regulatory duties within the Regulatory Affairs Department as required

Minimum Qualifications:

- BA/BS or equivalent education with 2-3 years of relevant experience in Regulatory Affairs
- 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