JOB DESCRIPTION

Position Title: Manager, Regulatory Affairs & Operations

Job Summary

The Regulatory Affairs & Operations Manager will be primarily responsible for submission publishing activities, publishing vendor oversight and implementation/updating of regulatory systems. The position also provides support of routine regulatory submission content and clinical labeling.

This role will provide operational expertise for dossier publishing; managing the logistics, planning, preparation, quality assurance, and delivery of regulatory submissions in compliance with Regulatory agency requirements, company standards, and timelines. For regulatory affairs aspects, this role will be responsible for supporting routine submissions such as routine IND monthly clinical submissions, IND/NDA annual reports, clinictrial.gov maintenance and clinical trial labeling.

Responsibilities

- Manage regulatory dossier/report publishing activities for Cymabay development products
- Maintain and oversee relationship with regulatory operation submission publishing vendor and serve and the primary regulatory contact for publishing activities.
- Working with the Regulatory Affairs submission team, prepare high-quality regulatory dossiers (electronic/paper) according to health agency requirements and guidance.
- Conduct QC of submission documentation and published dossier for technical completeness and compliance with health agency requirements
- Partner with project teams (Regulatory Affairs and contributing business functions) supporting effective submission planning, building and dossier delivery activities.
- Maintain regulatory submission archives and correspondence files and logs
- Assist in implementation, and use of company style guide and formatting requirements for submission-ready documents compliant with internal and health agency requirements.
- Perform Regulatory Information Management tasks including file transfer, storage, tracking, and archival of Regulatory submission documentation
- Remain current on relevant health agency requirements, submission standards, software validation concepts, and publishing best practices. Assess impact of regulatory changes to current working practices.
- Lead and/or coordinate the development or update of regulatory processes (SOP, Work Instructions and internal guidelines) for submission preparation (electronic or paper), QC, and regulatory information management
- Assist in identification of potential future systems and tools within Regulatory (eDMS, Publishing, eCTD Validator and Viewer, Authoring Templates, Acrobat Plug-in tools, ESG) to support evolution of regulatory operation systems.
- Assist in the review of clinical trial packages for site activation and monthly investigator submissions to INDs

- Assist in the compilation of annual and/or other routine reports (IND/CTA, Orphan application, annual SME renewal etc.)
- Ensure registration of clinical trials in clintrial.gov and EudraCT, and routine updating in accordance with regulatory requirements
- Working with Quality Assurance, conduct and maintain clinical labeling review
- Contribute to the maintenance of system documentation throughout the lifecycle of regulatory systems.

Qualifications

- Minimum H.S. Diploma with additional regulatory professional training in regulatory affairs. BS or better preferred
- Minimum of 5 years Pharmaceutical industry experience; preferably within the Regulatory Affairs/Operations function with knowledge of health agency requirements
- Experience compiling drug (IND/CTAs, NDA/BLA) submissions in the US and Europe; Other International submissions experience is a plus
- Experience with compiling submission dossiers in electronic (eCTD/eCopy)
- Proficient in using MS Office Suite, Adobe Acrobat and plug-in tools, eDMS and Publishing systems
- Strong organizational skills, communication and interpersonal skills, and attention to detail
- Demonstrated ability to manage priorities, multi-task and follow projects through to completion
- Must be comfortable working with changing timelines, scopes and priorities
- Good understanding of cGMP and FDA regulations and guidelines relating to CMC-related areas
- Experience in the conduct global clinical trial programs including phase 3.
- Possesses excellent teamwork skills, able to work in a matrix project team setting and a proven track record establishing and achieving clear and consistent goals and objectives.
- Excellent verbal and written communication skills.

Compensation

An appropriate financial package will be developed for the successful candidate to include a competitive base salary and equity, with a performance related bonus opportunity.

Work Environment

This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally on occasion is required, it is anticipated that this will be 10-15% of work time.