JOB DESCRIPTION

Position Title: Director CMC Regulatory

Job Summary

The Director of CMC, Regulatory will report to the SVP of Regulatory Affairs & Quality Assurance. The Director of CMC is accountable for the development and implementation of global regulatory chemistry, manufacturing and control (CMC) strategies for small molecules products from development through marketing approval for the US and EU markets. The individual will also be responsible for regulatory leadership, support and preparing CMC aspects of US IND, NDA and global regulatory submissions, ensuring compliance to all applicable regulations and standards. In addition, he/she will interface with Regulatory Agencies, such as FDA, Notified Body and competent authorities as required, maintain regulatory correspondence and submissions/registrations, and maintain knowledge in US and international pharmaceutical and combination product regulations.

Responsibilities

- Participates in cross-functional product development teams, development of regulatory strategies and support for CymaBay development programs, marketing applications and post-marketing activities.
- Assists in the responsibility for regulatory project timelines and management of IND/NDA and global regulatory submissions.
- Lead regulatory activities including planning, drafting, reviewing and submission of chemistry manufacturing and control (CMC) sections of regulatory submissions.
- Ensure compliance with FDA and international regulations and guidelines.
- Support IND and NDA applications including responsibility amendments, supplements, and annual reports.
- Provide global CMC regulatory guidance, especially as it pertains to current thinking related to small molecule products.
- Provide proactive CMC regulatory intelligence in areas of a competitive nature and keep abreast of changes in agency regulations and requirements (e.g. FDA, EMEA, ROW).
- Maintain well-organized, auditable regulatory files.
- Provide regulatory support for quality assurance and regulatory compliance activities.
- Provide regulatory guidance regarding analytical methods and requirements pertaining to combination products.
- Provide regulatory assessments for anticipated analytical, manufacturing and packaging changes.
- Support RA functional area in the review and approval of document control changes.
- Responsible for developing and maintaining department SOPs with an emphasis on drug regulations.
- Perform other duties as needed

Qualifications

- BS/MS or PhD in relevant discipline
- A minimum of 10 years of experience in CMC regulatory project management, development, scale-up and clinical/commercial development and manufacturing in the pharmaceutical industry
- Experience in research, process development, and manufacturing
- Extensive experience in leading small molecule processes and analytical development
- Good understanding of cGMP and FDA regulations and guidelines relating to CMC-related areas
- Knowledge of global CMC-related regulatory requirements and guidelines an advantage
- Excellent leadership, managerial and communications skills in a cross-functional environment
- Proficiency in analysis of scientific data and results with ability to review scientific documents including reports, publications and regulatory submissions
- Experience in the conduct of global clinical trial programs including Phase 3
- Demonstrated consistent achievement of team delivery against commitments and goals
- A strategic thinker and creative problem-solver capable of identifying risks and risk mitigation strategies
- Possesses excellent teamwork, negotiation and influencing 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
- Strong scientific writer and oral presenter
- Courage to be an “out of the box” thinker, to take on calculated risks, and champion new ideas and approaches with the development team

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.