JOB DESCRIPTION

Position Title: VP Clinical Development

Job Summary

The Vice President, Clinical Development will report to the Chief Medical Officer. The incumbent in this position may represent the Company to the medical community, clinical investigators, regulatory authorities, and business partners. The incumbent needs to perform well and be comfortable in a small biotech/start up environment.

This is a key position within CymaBay that will directly impact the success of the company. This position is responsible for establishing and executing the clinical development strategy for the Company's product pipeline. This incumbent's responsibilities will include but not be limited to overseeing the design and execution of clinical trials – Phase 1 to Phase 3; leading and managing the Clinical development team in support of regulatory submissions to successfully advance clinical pipeline to regulatory approval.

Responsibilities

- Manage a team of clinical development professionals responsible for designing clinical trials and executing the clinical and regulatory strategy in support of drug development for early and late-stage drug candidates.
- Will be directly responsible for building, managing, and mentoring a clinical science team to support clinical development programs across therapeutic areas.
- Lead and build the Clinical Development Team that will ultimately include, clinical operations, biostatistics, medical monitoring, drug safety, and other necessary functions.
- Partner with Regulatory Affairs on the development of clinical and regulatory strategy and represent the clinical team in regulatory interactions.
- Partner with Discovery, Preclinical, CMC, Medical Affairs, Commercial, etc. - on the development and refinement of the product profile and commercialization strategy throughout the product life cycle.
- Ensure adherence to GCP/ICH standards and internal SOPs in the conduct of clinical trials.
- Responsible for the clinical development plan for all clinical development programs.
- Work with medical affairs other team members to prepare publications and presentations for external meetings as well as maintain responsibility for clinical sections of regulatory documents (IB, IND sections).
- Responsible for the management and governance of external vendors involved in the design and clinical trials.
- Working with the CMO, may partner with business development on the evaluation and in-licensing/acquisition of external product development opportunities in alignment with the Company's focus in establishing a first class and diverse product development portfolio.
- Supports the company in establishing and maintaining a work environment focused on quality and that fosters learning, respect, open communication, collaboration, integration, and teamwork.
- Other duties as assigned.

Qualifications

- MD with 10 – 15 years relevant experience in the pharmaceutical or biotechnology industry.
- Experience with multiple therapeutic areas required and experience in liver disease would be a plus.
- Broad and extensive clinical development experience across all phases of product development and in multiple indications. Phase 3 experience and experience with drug registration are required and rare disease experience is preferred.
- Proven successful track record in leading and managing high performing teams to obtain regulatory approval in the US and the EU.
- A thorough knowledge of FDA regulatory requirements and ICH/GCP guidelines are essential as well as knowledge of ex-US regulatory processes.
- Experience in the design and conduct global clinical trial programs.
- Must possess the ability to provide scientific and clinical expertise to a clinical development program and evaluate scientific and clinical strategies to obtain regulatory approval with an entrepreneurial spirit.
- Proven success in executing clinical development strategies, identify core issues and obstacles for the clinical development of a designated indication and to critically evaluate outside expert advice.
- Demonstrated consistent achievement of team delivery against commitments and goals.
- Proven experience in managing and recruiting high performing talent.
- 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.
- Experience with communication of company goals and objectives to investors and partners.

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.