JOB DESCRIPTION

Position Title: Medical Director

Job Summary

The Medical Director will report to the Vice President of Clinical Development. This position is responsible for planing and directing all aspects of CymaBay's medical policies, standards, and programs as well as to design, implement and monitor clinical studies. The incumbent will also interact with data management personnel to plan data entry and analysis; recruit/screen/select competent investigators; organize investigator meetings; ensure that Good Clinical Practices (GCPs) are followed; ensure timely completion of studies; monitor data for safety and efficacy trends by reviewing clinical data; and write clinical reports upon completion or termination of studies. They will review requests of Investigational New Drugs (IND) studies, and provide input for pharmacokinetics and pre-clinical studies; prepare clinical portions of INDs, New Drug Applications (NDAs) and Biological License Applications (BLAs), including protocols, investigator brochures, medical reports, efficacy and safety summaries, scientific rationales and benefit/risk ratios.

Responsibilities

- Participates as key member of CymaBay's Clinical Development Team (CDT) to develop and maintain a strategic plan for the controlled growth, expansion, and/or development of programs and sites
- Solves existing and anticipated organizational problems and formulate and/or revise policies that will enhance the achievement of the organization's goals. Attends all CDT meetings with the overriding and ongoing goal of integrating clinical and non-clinical aspects of program operations and services.
- Manages administrative responsibilities such as clinical budget/finance management, and personnel management for clinical staff. In collaboration with other members of the CDT, uses a solutions-oriented approach to solve personnel issues in a timely manner including performance failures and violation of standards of care or personnel policy.
- Performs due diligence in matters related to clinical practice in full compliance of the medical licensing board, the CA business and professions code, HRSA Office of Regional Operations (ORO / OPR), and other regulatory agencies.
- Responsible for establishing systems of accountability for all providers to include productivity benchmarks, performance measures and controls for clinical quality assurance. Documents clinical protocols in a manner that is easily understood and can be followed by all clinical staff. Performs hands-on training of new and developing Clinical practices based on changes in regulatory or best practices.
- Participates in the recruitment of qualified clinical staff including interviewing and recommendation for hire. Monitors and assists with the new-hire orientation process to ensure consistency in training among all clinical providers.
- Ensures medical services and operations are in compliance with all applicable regulatory and licensing agencies. Assesses all matters of clinical compliance and provides timely recommendations for corrective action and quality improvement. Provides guidance and

supervision of clinical laboratory operations to ensure compliance with CLIA and other agency requirements.

- Responsible for removing barriers to achieving quality in medical care and for reporting to internal and external committees and entities, as required.
- Establishes and/or maintains working and collaborative relationships in the health provider community.
- Represents CymaBay and develops relationships with investigators, key opinion leaders and advisory bodies.
- Works closely with VP Clinical Development to provide direction regarding all clinical issues related to managed care.
- Develops protocols and case report forms, which will provide adequate efficacy and safety information for Phases 1-3 of clinical trials.
- Provides direct clinical medical services in the area of board certified (or board eligible) medical specialty in accordance with the highest applicable standards of medical and professional practice and in full accordance with health center protocols and policies.
- Provides additional assistance within and outside of clinical arena, as requested and/or as appropriate, to ensure the ongoing success of CymaBay.
- Ensures all clinical programs are in compliance with all applicable regulations.

Qualifications

- MD/PhD with 5-8 years relevant experience in clinical research in the pharmaceutical or biotechnology industry.
- Board certification, or Board eligible, in a major primary care specialty field of practice
- Strongly prefer a minimum of three years experience in progressively responsible administrative or management-related positions within a primary health care environment.
- Experience with liver disease and broad specialty required (e.g. infectious disease, nephrology, pediatrics, cardiology, etc) and experience in rare disease is preferred.
- Broad and extensive clinical development experience across all phases of product development and in multiple indications. Phase 3 experience is required.