Quality Assurance Manager

Reports to: Director, Quality Assurance Operations

Classification: Exempt

Summary:

Oversee quality operations associated with CymaBay's Clinical Programs and ensuring quality compliance at contract manufacturing compliance organization (CMO) sites.

Responsibilities include, but are not limited to, coordinating resolution of quality related issues, review of change controls, QA lot disposition, compilation of trending reports, and assisting with quality investigations and product complaint investigations to ensure compliance with applicable regulations and regulatory commitments. This includes the quality oversight of contract vendors, and lot disposition to ensure on-going compliance with applicable regulations and regulatory commitments.

Essential Functions and Job Responsibilities:

- Responsible for the daily management of CMO quality relationship
- Quality representative for CMO telecons, correspondence and person-in-plant
- Oversee quality investigations to determine root cause and assure timely resolution
- Ensures appropriate corrective and preventative actions are implemented and tracked as part of investigations
- Ensures product and process related changes are tracked and approved through change control in cooperation with CMO
- Review product development documents, protocols and reports from quality perspective for adherence to applicable regulations and regulatory commitments
- Responsible for quality oversight of cGMP activities for drug product manufacturing, labeling, batch record review and lot disposition
- Independently perform and manage batch release activities for clinical production including but not limited to review of batch records, analytical data, certificates of analysis, and other documents (e.g., method validation protocols/reports, product specifications, etc.) as needed for consistency with applicable regulations and for compliance with CymaBay's GMP Quality System
- Provide quality assurance support, guidance and direction to CymaBay's internal manufacturing and quality teams operating under cGMP regulations
- Provide status reports and quality metrics to support management review process
- Perform QC of data that supports regulatory submissions
- Establish collaborative relationships with internal and external stakeholders to ensure timely documentation and resolution of quality issues
- Complete other responsibilities, as assigned

Minimum Qualifications:

- Bachelor of Science degree in scientific field (advanced degree a plus)
- Minimum 7 years' experience in the pharmaceutical / biopharmaceutical industry and 2 years direct experience in quality operations; preferably with external CMOs
- Thorough understanding of current GMP regulations, ICH guidelines, and industry practices
- Experience with cGMP manufacturing of clinical trial and commercial products
- Decision making experience for a GMP manufacturing site
- Experience leading deviation and non-conforming material investigations
- Experience managing and partnering with outside CMOs is preferred
- Proven technical writing/editing skills and problem-solving ability
- Ability to self-direct and adapt to changing priorities
- Experienced with regulatory agency interactions, a plus
- Strong attention to detail and excellent organization skills
- Good verbal, written, and interpersonal communication skills
- Ability to travel 10% domestically