Director, Quality Assurance Operations

Reports to: Vice President of Quality

Classification: Exempt

Summary:
Oversee quality operations associated with CymaBay's Clinical Programs and ensuring quality compliance at multiple manufacturing sites. This role is expected to provide leadership for maintaining and enhancing, in a phase-appropriate manner, the quality and compliance culture.

Responsibilities include, but are not limited to, coordinating resolution of quality related issues, review of change controls, QA lot disposition, compilation of trending reports, writing quality investigations and assistance with product complaints investigations to ensure compliance with applicable regulations and regulatory commitments. This includes the quality oversight of contract vendors, and QA lot disposition to ensure on-going compliance with applicable regulations and regulatory commitments. The Director of Quality Assurance Operations will also be responsible for assisting with GMP compliance activities by reviewing and evaluating compliance issues/concerns/risks within the organization.

Essential Functions and Job Responsibilities:

- Responsible for quality oversight of cGMP activities which include setting up and/or optimizing processes for, drug substance and drug product manufacturing, labeling, batch record review and lot disposition
- Provide direction for complex deviations and other investigations and CAPAs in support of batch release, inspection readiness and regulatory findings including tracking closure of compliance issues
- Independently perform and/or 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 company's GMP Quality System
- Provide quality assurance direction, support, and guidance to internal manufacturing and quality teams operating under cGMP regulations
- Provide status reports, including relevant quality metrics and participate in the management review process
- Identify and support continuous improvement projects in collaboration with CMC, QC and RA to achieve quality, reliability and efficiency improvement objectives
- Manages quality operations team
- Establish collaborative relationships with internal and external stakeholders to ensure all quality and compliance matters and any issues that arise are addressed in an open and timely manner
- Complete other responsibilities as assigned

Minimum Qualifications:

- Bachelor of Science degree in a scientific field (advanced degree a plus)
- ASQ Certification a plus
- Minimum 8-10 years' experience in the pharmaceutical / biopharmaceutical industry and 4 years direct experience in Quality managing CMOs

- Thorough understanding of GMP regulations and industry practices
- Expert knowledge of cGMP manufacturing including small molecule active pharmaceutical ingredient and drug product manufacturing
- Experience with cGMP manufacturing of clinical trial and commercial products
- Proven managerial skill and ability to lead and work in a lean team setting within an organization and with external CMOs
- Demonstrated knowledge of quality systems that support deviations, CAPA and change control
- Experience leading deviation and non-conforming material investigations
- Proven track record of managing and partnering with outside vendors including CMOs and/or CROs
- Proven technical writing/editing skills and problem-solving ability
- Ability to self-direct and adapt to changing priorities
- Experience with regulatory agency interactions
- Strong attention to detail and excellent organization skills
- Good verbal, written, and interpersonal communication skills
- Proficiency in Microsoft Office applications
- Ability to operate in a fast-paced, multi-disciplinary environment
- Ability to travel 20% domestically and internationally