JOB DESCRIPTION

Position Title: Senior Quality Assurance Specialist

Job Summary

The Senior Quality Assurance Specialist will be responsible for administering the Quality Assurance systems at CymaBay. The position will mainly provide quality support for the manufacturing of drug substances and drug products at contract manufacturing organizations (CMOs) to ensure that manufactures drug products are release timely and in compliance for the intended use. This position will provide oversight of CMOs and liaison of quality related issues with CymaBay CMC team. This position is responsible for coordinating and managing the day to day quality activities to meet cGMP and regulatory requirements.

Responsibilities

- Perform review of executed batch record, test records and other documents to enable drug substance and final drug product release, certifying as GMP compliant
- Perform product disposition activities which are aligned with CymaBay operational functions to ensure the timely supply of drug substance and drug product that meets clinical /commercial customer requirements while ensuring compliance with testing standards, SOPs, validation guidelines and regulatory filings
- Review and approval analytical methods and validation protocols and reports
- Review of exception reports and oversight of its adequate and timely completion
- Resolution of quality issues and deviation investigation, including verification of CAPA and follow up actions
- Assisting in the development and management of internal quality systems
- Perform quality oversight of multiple contract manufacturing and testing organizations, interacting with CMOs and develop a single team partnership environment
- Oversee and resolve quality issues at third party organization
- Perform quality trends analysis and reports, recommending continual improvements opportunities
- Work close with CMC team, review of QC data related to product release and stability activities
- Work with CMC and clinical teams, providing assistance as required to ensure IMPs arrive at clinical sites in time to support aggressive timelines

- Support qualification/validation of equipment. Support process validation studies and technology transfer as needed
- Support GCP activities at CymaBay as required
- Budget assessment and contract negotiations, training and oversight for all DM services from study start-up through study close-out and final reporting
- Responsible for managing and tracking work orders associated with clinical DM activities to ensure that the operating costs for the DM department are achieved within budget

Required Skills and Abilities

- Strong experience with batch records review and in-depth knowledge of quality and regulatory requirements for the release of pharmaceutical products
- Strong technical knowledge of analytical and manufacturing technologies and processes
- Ability to work independently and communicate effectively with peers and management groups
- Work well independently and in a project team environment
- Ability to support internal and external compliance audits of suppliers, contract laboratories and CMOs
- Ability to identify compliance risk and recommend corrective actions
- Ability to author, review and approve SOPs and other controlled documentation for compliance with applicable regulations

Education and Experience

- Minimum B.S.degree in relevant scientific discipline e.g. Biochemistry, Microbiology, Pharmacy, Biological Sciences or Related Pharmaceutical Science

Knowledge/Skills

- Minimum of 7 years – experience in biopharmaceutical operations, with at least 3 years in Quality Assurance with expertise in manufacturing of drug substance and drug product
- Knowledge of FDA and ICH quality regulations with respect to all aspects of drug development, clinical and CMC
- Excellent verbal and written communication and interpersonal skills
- Proficient with computers and word processing software (i.e. 2007 Microsoft Office products)

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.