Job Description

Job Title: Manager OR Senior Manager, QC Stability

Department: Quality Assurance
Reports to: Senior Director, Commercial Quality Assurance

Summary/Objective

The Manager/Senior Manager will be responsible for all aspects of quality control in the production of commercial and clinical trial material. The Manager/Senior Manager will work with Puma's contract manufacturing organizations (CMOs) and contract testing laboratories (CTLs) to ensure that appropriate quality standards are met prior to the release of product. This position will collaborate closely with cross-functional departments to achieve corporate goals and objectives.

The successful candidate will have a good understanding of the regulatory drug approval process, is a self-starter with the ability to work under limited supervision, and is seeking to be part of an innovative team. This position will be instrumental in bringing the company's first product to commercial launch, and be a critical part of creating an innovation team for the development of the company's next generation of products.

Essential Functions

- Represent quality control in CMC project teams
- Collaborate with CMC core team to develop and implement manufacturing and regulatory drug substance and drug product specifications
- Manage review and approval of analytical method development and validation for use in release testing and stability of drug substances and drug products at CMO and CTL
- Manage project plans and their associated timelines
- Manage review and approval of analytical test data and stability reports generated at CMO and CTL
- Responsible for the management, maintenance and archival process of QC documents
- Perform deviation investigations and CAPA implementation of issues involving testing conducted by external and internal Quality staff
- Design and implement appropriate corrective actions as needed in a timely manner
- Manage review and approve changes to methods, processes and specifications for all programs
- Analyze and trend stability data for management review and prepare reports in support of regulatory (IND/IMPD/NDA/MAA) submissions
- Assist during inspections/audits (regulatory or internal) and audit observation responses

- Champion, lead and participate in continuous improvement activities for the quality control operations

- Support the development and management of quality metrics to optimize performance, productivity, and effective resource planning

Competencies

- Practical understanding of regulatory compliance requirements with the ability to provide applicable guidance to team members

- Outstanding written and verbal skills as well as problem solving skills

- Ability to work in a fast-paced and dynamic environment

- Self-motivated and able to prioritize projects in with short lead times

- Extensive expertise in wet chemistry and a variety of analytical techniques including HPLC, GC and spectroscopy to analyze materials and determine assay, purity, and impurity profiles

- Experience with technology transfer to third parties is desired

- Knowledgeable in global regulatory CMC documents and familiar with GMP's and ICH Guidelines

- Excellent oral and written communication skills, auditing skills, and proven ability to work autonomously and manage effectively in a matrix environment

- Proficiency in MS Word and Excel - Proficiency in other statistical analysis software desired

- High attention to detail, excellent organizational skills and the ability to work on multiple projects with tight deadlines

- Excellent interpersonal and verbal communications skills and the ability to deal effectively with a variety of personnel both internally and outside the company

Supervisor Responsibilities

This position may manage all employees of the department and is responsible for the performance management and hiring of any employees reporting to this role within that department.

Work Environment

This job operates in a professional office environment. This role routinely uses standard office equipment such as computers, phones, photocopiers, filing cabinets and fax machines.

Demands

The physical demands described are representative of those that must be met by an employee to successfully perform the primary functions of this position.

The physical demands of the office are normally associated with extended amounts of time sitting and using office equipment, including a computer, keyboard and mouse, which can cause muscle strain. While performing duties of this job, the employee is occasionally required to stand; walk; sit; use hands to finger, handle, or feel objects, tools or controls; reach with hands and arms; climb stairs; balance; stoop, kneel, crouch or crawl; and talk or hear. The employee must occasionally lift or move up to 25 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, depth perception and the ability to adjust focus.

Position Type/Expected Hours of Work

This is a full-time position. Days and hours of work are Monday through Friday, 8:30 a.m. to 5 p.m. This position regularly requires long hours and may require weekend work.

Travel

Travel is primarily local during the business day, although some out-of-area and overnight travel may be expected. Travel may be required

Required Education & Professional Experience

- Minimum of B.S. degree in a scientific discipline
- 8-10 years of progressive responsibility in a GMP quality control (including commercial) environment
- Comprehensive working knowledge of local, state, federal, and international regulations pertaining to GXP and ICH guidelines
- Thorough understanding of regulatory compliance requirements for US FDA, European Union, and Health Canada

Preferred Education & Experience

- Prior experience with Health Authority inspections a plus
- Experience working with Oracle Agile a plus
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Additional Eligibility Qualifications

- Experience in the biotechnology or pharmaceutical industry highly preferred
- Experience in Oncology highly preferred

Other Duties

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that ae required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.

Equal Opportunity Employer

Puma Biotechnology Inc is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, gender identity, sexual orientation, national origin, ethnicity, age, disability, veteran status, marital status, or any other characteristic protected by law.