Job Description

Job Title: **Associate Director, Commercial Quality Assurance**

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

Summary/Objective

The Associate Director of Commercial Quality Assurance leads and manages the quality operations activities for Puma, and assures overall compliance of all commercial manufacturing activities.

The Associate Director of Commercial Quality Assurance will have primary oversight of all quality aspects relating to drug substance and drug product manufacturing, testing, labeling, packaging, and distribution. This position will oversee lot release operations and work performed by Puma's Contract Manufacturing Organizations (CMO) and contract laboratories, ensuring timely delivery of quality products and services.

Essential Functions

- Serve as Quality Operations tactical lead on core Puma projects related to Chemistry, Manufacturing, and Controls (CMC), overseeing all QA operational compliance activities
- Provide leadership and direct the compliance oversight of Puma CMOs associated with commercial drug substance and drug product manufacturing
- Exercise judgement on complex quality issues using thorough understanding of quality philosophy and regulations
- Prepare written quality impact assessments related to product quality issue of Clinical Trial Materials and Commercial Products
- Organize, facilitate, and attend cross-functional meetings as the QA representative and Quality Subject Matter Expert (SME)
- Provide Quality support on process validation activities to support launch of late-stage and commercial materials
- Support commercial product and medical device disposition
- Manage and evaluate changes associated with commercial development products
- Support preparation and participate in regulatory inspections and internal audits
- Actively interface with and provide support to Global Supply Chain group to develop processes, and to meet compliance requirements from EU Qualified Persons and Canadian Person In-Charge.
- Approve specifications, analytical methods, technical reports, protocols, and SOPs to ensure compliance with cGMP and Puma internal procedures.
- Perform quality review of manufacturing documents, including batch records, deviations, investigations, complaints, changes, validation, and technology transfer documents.
- Relay product impacting quality issues such as, manufacturing changes, non-conformances, and product complaint systems to the Material Review Board (MRB) liaison.
- Ensure appropriate quality systems are in place to support product release in a compliant and timely manner, and routinely monitor performance in effort to optimize turnaround.
- Provide quality oversight in manufacturing team meetings

Competencies

- Practical understanding of regulatory compliance requirements with the ability to provide applicable guidance to team members
- Previous experience with analytical testing, test methods, and method validation.
- Team player attitude with experience contributing to multi-disciplinary project teams and be able to work with minimal supervision
- Outstanding written and verbal skills as well as problem solving skills
- Strong initiative and ability to assume significant project management roles
- Ability to work in a fast-paced , and dynamic environment
- Ability to travel domestically and internationally
- Strong communication skills with ability to work in cross-functional teams on assigned projects
- Self-motivated and able to prioritize projects in with short lead times

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.

Supervisor Responsibilities

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

Required Education & Experience

- Minimum of B.S. degree in a scientific discipline
- 10-15 years of QA experience working in commercial quality operations in the pharmaceutical or biotechnology industry, with specific experience in GXP quality assurance auditing and GXP regulations, or combined experience working in Quality control and/or Manufacturing
- Comprehensive working knowledge of local, state, federal, and international regulations pertaining to GXP and ICH guidelines
- Complete and thorough understanding of regulatory compliance requirements for US FDA, European Union, and Health Canada
- Prior experience with Health Authority Audits

Additional Eligibility Qualifications

N/A

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.

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.

Physical 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.

Travel

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

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.