Job Description

Job Title: Manager or Senior Manager, Pharmacovigilance

Department: Pharmacovigilance
Reports to: VP Pharmacovigilance

Summary/Objective

To provide proactive safety surveillance across the lifecycle of Puma products, Support development and execution of Risk Management Plans, Risk Assessment, and Risk Communications pre-and-post marketing.

Essential Functions

- Perform periodic aggregate safety data review according to a signal detection strategy and escalate possible safety issues to VP of Global Pharmacovigilance and Clinical/Medical Monitor as needed for assigned product(s)
- Collaborates with PV leader in the preparation DSURs, PSURs, PADERs, PBRERs as appropriate
- Monitor medical and scientific literature for published articles relevant to the safety profile for assigned product(s)
- Define search criteria (e.g., PT, SMQs), run validated database searches, and analyze data for safety signal detection in consultation with VP Pharmacovigilance and/or Clinical/Medical Monitor
- Plan and perform analysis in support of response to regulatory agencies, EC/IRBs and Investigators or ad hoc inquiries regarding safety issues
- Support development and execution of risk management plans, risk assessment, and risk communications
- Conduct safety data analysis in support of developing and updating safety sections of regulatory documents, Informed Consent, Company Core Data Sheets, product labels, etc.
- Provide support of developing and updating Investigator Brochures and study protocols
- Provide safety data analysis in support of Safety Review Committee (SRC)
- Manage the relevant day-to-day aspects of safety agreement with licensing and/or collaboration partners (CRO's)
- Lead efforts to improve processes and increase work efficiency applicable to the Safety Surveillance
- Remain in compliance with active Puma standard processes and procedures

If required:

- Execute triage for appropriate causality assessment on Individual Case Safety Report (ICSRs) for regulatory reporting
- Write narratives, review of SAE for clinical content, accuracy and completeness
- Create follow-up queries, and case follow-up measures for case processing
- Manage and ensure compliant safety reporting in accordance with local and international reporting regulations, and/or standard operating procedures

Competencies

- Must have the ability to work independent in a fast-paced results-driven environment
- Ability to make basic decisions (e.g., categorizing serious and non-serious adverse events, routine coding) with an understanding of the result and impact
- Proven ability to seek and utilize information and solve complex problems
- Excellent interpersonal skills in developing effective relationships with safety data customers and colleagues, with the ability to communicate with diverse individuals and groups

- Proficiency in the processing, assessment of safety data (pre-and-postmarketing)
- Proven ability to critically evaluate and summarize clinical and scientific data
- Demonstrated computer literacy, with proficiency in the used and management of safety databases, strong computer skills such as Word, Power Point, and Excel

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 BS/BA degreed in a health related (e.g., RN/BSN, RPh/PhrmaD) or biological science field (e.g., B.S. in Biology) and 3+ years of biotech/pharmaceutical experience in Drug Safety/Pharmacovigilance
- Minimum of 3-5 years in Pharmacovigilance & Risk Management
- Previous experience with adverse event reporting systems, FDA and EU drug safety/Pharmacovigilance requirements
- Experience in phase I-IV drug safety surveillance and preparation of investigational and post-marketing regulatory reports

Additional Eligibility Qualifications

- Experience with ARISg, MedDRA, WHO, ARGUS safety databases will be a plus

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 (up to 10%).

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