Job Description:

Title: **Sr. Director/Director, Global Regulatory Lead**

Department: **Regulatory Affairs**
Reports to: **SVP, Regulatory Affairs & Program Management**
Date: **22DEC017**

Summary/Objective

The purpose of this position is to support the global regulatory development and successful registration for assigned product, indication, and/or corresponding clinical studies. This position also may serve as the US regulatory liaison for the assigned clinical studies required to support the assigned indication; serves as the global regulatory lead on the Product Development Team; responsible for development of the global registration strategy (plan) to support the assigned indication; execution of the global registration plan; management of the global regulatory team; and submission of the respective NDA/BLA/MAA for assigned product/indication.

Essential Functions

Responsible for all regulatory affairs activities required to support the development and registration of the assigned product for the assigned indication/study, including:

- Provide US regulatory intelligence and strategic global regulatory strategy input (i.e. Global Strategic Regulatory Plan) to support the rapid development and timely registration for the assigned product/indication;
- Working with the project Global Regulatory Leads, responsible for the strategic regulatory interactions globally, including: strategic imperatives; development (writing) of the required strategic regulatory documents, including ensuring alignment with agreed strategic regulatory strategy and/or prior regulatory agency input, represent strategic regulatory input at Health Authority meetings;
- Responsible for representing global regulatory affairs strategic input to the Product Development Team for assigned product/indication;
- Identify and implement required processes/procedures for Global Regulatory Affairs – Strategic and Liaison function as required;
- Responsible for establishing and managing the regional regulatory leads (EX-US) through establishment of the regional Regulatory Management Plan and associated contracts/work schedules;
- Where assigned a specific project as part of the overall regulatory project (product/indication):
  - Responsible for the management of the assigned/contracted Regional Regulatory Lead(s) with respect to tactical aspects of the global regulatory CTA/MAA submissions to support the assigned project;
  - Responsible global regulatory representative on the respective Study Team responsible for delivering the required studies for the assigned product/indication;
  - US regulatory representative for the assigned product/indication with respect to quality and completeness of all regulatory communication and submissions (i.e. routine submissions, meetings, SPAs, etc.);
- Responsible to be knowledgeable of and comply with all Puma RA processes/procedures;
- Perform other related duties as assigned

Skills & Abilities

- Excellent communication skills (e.g., clear & concise), team player, proven negotiation skills;
- Excellent understanding of pharmaceutical development, clinical research, study design, biostatistics, pharmacokinetics, the US regulatory environment, project management and medical terminology;
- Excellent time and project management skills;
- Excellent critical and logical thinking with ability to analyze problems, identify alternative solutions and implement recommendations for resolution;
- Self-motivated, flexible & creative leader, able to prioritize, multi-task and work in a fast-paced and demanding environment;
- Able to take ownership of a given assignment, proactively consulting other project team members and other department representatives for information or guidance, as necessary
- Able to understand and interpret data/information and its practical application

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.

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 association with extended amounts of time sitting and using office equipment, including a computer, keyboard and mouse, which can cause muscle strain. While performing the duties of this job, the employee is frequently required to stand, walk and sit. Periodic light lifting of supplies and materials may apply. Work is performed in an office environment.

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 (up to 20%) both domestic and international

Required Education & Professional Experience

- Doctorate degree –or– Master's –or– Bachelor's degree with appropriate level of pharmaceutical industry and regulatory affairs experience
- Degree(s) should be in Life Sciences/Health Related Sciences from an accredited college or university
- Successful submission, approval, and post-approval management of an NDA/MAA/NDS in 1 ICH region (Associate Director) or 2 ICH regions (Director).
- Prior experience as a Global Regulatory Lead responsible for the execution of a global development program in oncology.
- Full functional knowledge of regulatory requirements (Directives, Regulations, and Guidance, including ICH) for 2 ICH regions pertaining to the development and registration of drug products.
- Ability to mentor/coach manager level GRL's with respect to both strategic and tactical regulatory affairs for 1 region.
- Serve as a resource with respect to both strategic and tactical regulatory affairs for 1 region, including mentoring/coaching manager level GRL's.

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.

Employee

Signature_____ Date_____

Print Name _____ Title_____

Supervisor

Signature_____ Date_____

Print Name _____ Title_____