



Job Description

Job Title: Senior Director, Medical Communications

Department: Medical Affairs

Reports to: Vice President, Medical Affairs

Date: 11NOV2016

Summary/Objective

The Senior (Sr) Director, Medical Communications will be responsible for developing clinical/scientific communication, publication strategies and tactical execution plans to engage Health Care Professionals (HCPs), Medical Organizations, Patient Advocacy Groups and other groups involved in patient care via appropriate medical communication activities. In order to deliver cutting edge data and technical/practical education to HCPs, the Sr Director will be well-versed in clinical practice, as well as basic and clinical research. The Sr Director of Medical Communications will report to, and work closely with, the Vice President (VP) of Medical Affairs to provide strategic and operational support for executing Medical Affairs goals and objectives.

The Sr Director of Medical Communications will manage Puma Biotechnology's Medical Communications Department, including Medical Information and Publications, which develops communiqués for and fulfills inquiry responses from HCPs on Puma Biotechnology's products in accordance with all federal regulations. This will include coordinating the intake of calls during business hours and after hours, as appropriate, fulfilling business replies and phone requests for product information, and developing novel informational projects to fulfill and clarify product information better for the healthcare community. In addition, the Sr Director of Medical Communications will be responsible for all publication activities for Puma-sponsored Phase IV trials and for supporting publication activities for Investigator-Sponsored Trials, ensuring alignment to both Medical Affairs and Commercial messaging and strategies. All of these activities will include key opinion leaders, medical professionals and decision makers at organizations such as Pharmacy and Therapeutics, Formulary and Managed Care Committees.

Essential Functions

- Responsible for cross-functional development, implementation, delivery and maintenance of Global Publication Plan and Global Medical Communications Programs that support neratinib and therapeutic areas of interest
- Implement appropriate publication strategy and provide ideas for generating abstracts and manuscripts of scientific, clinical and strategic interests
- Provide medical leadership for scientific review and approval of communication materials and medical materials in compliance with corporate policy, company standard operating procedures and government/industry regulations

- In support of medical communication objectives, foster the establishment and maintenance of relations with key external thought leaders
- Represent Puma Biotechnology at Medical Meetings, Conferences, Advisory Boards, and in interactions with thought leaders
- Participate, as needed, in global and national Advisory Boards to gain insights on medical communication gaps about Puma Biotechnology, neratinib and therapeutic areas of interest
- Provide Medical Affairs support to review requests for grants and sponsorships
- Ensure that Puma Biotechnology review and approval processes strictly follow all compliance guidelines
- Participate in long-range planning; develop and manage project plans, assess resource needs, and work cross-functionally to develop and implement processes and standards
- Coordinates, manages, and optimizes Call Center vendor activities
- Manages and optimizes Call Center and departmental budgets
- Manages Home Office triage phone system in concert with administration management for optimal customer inquiry fulfillment
- Assures compliance with all documentation and retention policies
- Assures receipt and processing of all Medical Information inquiries
- Interprets and clarifies all requests which include direct, phone or email contact with clinicians or internal stakeholders
- Develops and updates standard and individual response letters as needed
- Ensures satisfaction for internally and externally generated inquiries and serves as an expert source of information on neratinib
- Evaluates, analyzes, and responds to inquiries in an accurate, balanced, and timely manner according to all SOP and regulatory guidelines
- Maintains robust cost-effective drug information resources to answer inquiries
- Collaborates with authors (both external and internal), medical writers, and others on publication development and generation and provides operational project leadership
- Manages the publication development process, including budget and vendor responsibilities
- Coordinates intelligence at scientific congresses which will include monitoring, organizing, and posting content of importance to Puma Biotechnology
- Serves as a Medical Information resource at scientific meetings when called upon (i.e. Medical Affairs Booth)
- Performs interpretive literature searches and becomes adept at where to find most likely resources to address questions on neratinib
- Develops cost-effective knowledge of management systems for internal utility
- Maintains current awareness of published literature, regulations, guidelines, procedures and practices as it relates to competitor products, as well as neratinib and diseases for which we have an interest

- Optimizes and communicates the value and application of Medical Information Services to both internal and external shareholders
- Develops collegial relationships with Commercial colleagues and understands the needs of the market as it relates to the provision of medical information
- Provides medical Information due diligence as needed to Business Development and Marketing
- Serves on appropriate internal committees and special project teams as assigned by VP, Global Medical Affairs. Serves as key resource for Field Medical Affairs.
- Assists in carrying out strategy to ensure clear and consistent communication, and provides assistance to ensure that publication and presentation timelines for conferences and medical publications are met
- Monitors the competitive environment for advances and trends in our therapeutic areas, including new treatment management and new therapies, competitive products and features and provides feedback to the f on specific initiatives of competitor's initiatives
- Provides medical input and may be called to participate in the Medical Review Committee (MRC) and/or as the Medical Lead on the Promotional Review Committee (PRC) for all promotional and external marketing materials. Assures medical accuracy of all materials with particular emphasis on background materials as they relate to quotes and interpretation from the medical literature.

Competencies

- The management of Medical Communications, including budget, projects, vendor(s), and personnel
- Demonstrated ability to manage a budget and assure appropriate deployment of resources toward communications that are compliant with Puma Biotechnology SOPs and all applicable regulatory guidelines to ensure medical and scientific accuracy and fair balance
- Build and manage relationships with internal and external contributors
- Ensure the scientific integrity, quality and accuracy of all deliverables
- Maintain knowledge of product areas, current trends, and literature
- Commitment to ethical practices in the preparation and dissemination of publications, including conference materials
- Ensure compliance with all applicable laws, regulations, and policies
- Develop and/or maintain applicable policies, guidelines, and work practices and revise as needed to be consistent with standard practices; educate and train internal contributors as needed
- Excellent ability to interpret and present scientific and clinical medical data to a variety of audiences, along with a strong understanding of statistics
- Demonstrated innovation and creativity in production of work deliverables and methods to optimized data disclosure in a timely, appropriate, and effective manner
- Knowledge of and responsibility for collaboration within all functional areas within Puma Biotechnology is required. Specifically, within the Medical Affairs department a working knowledge of Medical Publications, Medical Information Databases, Field Medical Roles, Research Grant

Processes, Continuing Education and Regulatory/Compliance issues as they relate to the effective dissemination of scientific information is required

- Demonstrated ability, or potential, to excel in smaller entrepreneurial organizations
- Exceptional oral and written communication and interpersonal skills (including demonstration of ability to network)
- Ability to understand, integrate and effectively communicate scientific/medical and commercial value of Puma Biotechnology's products to the medical community and other key internal and external audiences.
- Knowledge and understanding of Managed Care distribution channel
- Knowledge and understanding of Clinical and Regulatory Guidelines
- Knowledge and understanding of compliance in commercial settings
- Ability to travel up to 10%, in order to attend regional and international conferences/workshops to obtain new competitive information, and keep abreast of clinical trends
- Ability to respond appropriately to needs of key stakeholders and manage expectations
- Demonstrated excellent project management skills and follow through
- Must have excellent PC skills and be familiar with current clinical software, all literature search databases and tools

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 %).

Required Education & Professional Experience

- Minimum of PhD or PharmD is required with demonstrated expertise at the highest level in the provision of Medical Information and publication planning

- MBA is an asset
- Minimum of 7 years of experience in the provision of Medical Communication or related positions either in the Biopharmaceutical Industry or Pharma with demonstrated management and leadership abilities required
- Oncology experience strongly preferred
- Strong leadership, planning and project management skills, along with the ability to be productive with minimal supervision
- Proficiency with standard software including Microsoft Office, PubMed, Endnote, and DataVision is preferred

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 are 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.