Your Generics & Biosimilars Industry

JOB DESCRIPTION

Position Title: Vice President, Sciences & Regulatory Affairs

Department: Sciences & Regulatory Affairs

Report To: Senior Vice President, Sciences & Regulatory Affairs

FLSA: Exempt

Last Revision Date: 2022 03 01

Job Summary: The VP, Sciences & Regulatory Affairs creates and implements strategic plans to drive key Sciences & Regulatory Affairs (SRA) priorities. The position leads AAM Working Groups and Task Forces in all aspects of GDUFA and BsUFA from negotiations to implementation, as well as key topic initiatives as raised by FDA and/or member companies. The VP, Sciences & Regulatory Affairs is the primary point of contact to all relevant domestic regulatory agencies and member company regulatory executives.

Essential Duties and Responsibilities:

- Lead the development of strategy to achieve desired outcomes on AAM priorities, FDA and USP initiatives and member company requests.
  - Define and operationalize initiatives arising from FDA activity and member-company issues.
- Oversee consultants and member company representatives as assigned to specific projects.
- Lead the Member Sciences & Regulatory Affairs Initiatives.
  - Create strategy, frame industry position, and document implementation plans
  - Convene SMEs from member companies to build strategy, define plans and address issues.
  - Facilitate discussion and action of members and FDA, convening discussions as appropriate, and guide staff/consultant activity to achieve results.
  - Collect and evaluate requests and recommendations from members for issues and projects.
- Lead all GDUFA and BsUFA activities including negotiations, implementation, and episodic issues.
- Serve as the primary liaison and point of contact for AAM and member companies representatives to relevant agencies and organizations including FDA, USP and global regulators.

- Oversee the activity of all working groups and task forces being coordinated by SRA staff to ensure strategy is consistent with AAM priorities.
- Develop/create all SRA-hosted conferences and workshops; incorporate member company and FDA/USP input. Responsibilities include but are not limited to guiding speaker/panel selection, serve as the lead for FDA, USP and member company representative on the planning committee, and supervise all staff and consultants in preparation for events.
- Coordinate information needs of member companies with FDA, envisioning and implementing regular communications and education opportunities on new initiatives, trends and issues.
- Perform other duties as assigned consistent with the goals of AAM.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Extensive knowledge of the regulatory process and regulatory issues of the generic pharmaceutical industry.
- Ability to be diplomatic, resourceful and persuasive.
- Ability to anticipate challenges and effectively resolve conflict by identifying opportunities.
- Ability to work creatively and with flexibility in a fast-paced environment while maintaining high work standards.
- Ability to work independently as well as collaboratively with internal and external stakeholders, a keen sense of protocol.
- Ability to prioritize and manage multiple initiatives simultaneously.
- Ability to take responsibility for assignments, develop a strategic vision and see them through to a successful completion, with little oversight.
- Ability to develop rapport and engender trust, transparent.
- Ability to inspire and motivate constituents, build consensus.
- Ability to balance multiple requirements of internal and external constituents with a flexibility and a steady temperament.
- Exceptional written and verbal communication skills.
- Exceptional organizational and project management skills for timely implementation of projects involving multiple functions and external resources.
- Exceptional interpersonal skills, a focused listener.
- Exhibits a positive attitude and professional demeanor.
- Exhibits a high degree of personal initiative.
- Effective negotiation skills.

Education and Experience Requirements:

- Advanced degree in science-related field (i.e., Pharm.D. Ph.D., etc.), required.
- 10+ years of experience in science-related role with 5+ years in regulatory agency and/or pharmaceutical regulatory organization, required.
- 3+ years of supervisory experience, required.
- Experience with ANDA development and filing preferred.

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- None

Work Environment: The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Standard office environment

Travel: up to 25%