Your Generics and Biosimilars Industry

JOB DESCRIPTION

Position Title: Director, Sciences & Regulatory Affairs

Department: Sciences & Regulatory Affairs

Report To: SVP, Sciences & Regulatory Affairs

Job Summary: The Director, Sciences & Regulatory Affairs is responsible for working with the Association for Accessible Medicines (AAM) Science & Regulatory Affairs team, members of the Sciences and Regulatory Advisory Working Group (SRAWG), and other Scientific Affairs personnel including Member companies on the development of AAM's Scientific Affairs initiatives to Member communications and training opportunities for these initiatives.

Essential Duties and Responsibilities:

- Serve as the project manager on assigned components of Science & Regulatory Affairs (SRA) strategy to influence regulatory policy and practice. This includes but is not limited to gathering information on new guidance, trends and anticipated issues, identifying sources of research and policy analysis, contributing to strategy development and execution, and drafting documents.
- Manage meetings and activities in support of SRA priorities.
- Represent AAM in assigned external meetings and forums, particularly at FDA, and document proceedings and share with AAM's SRA team.
- Contribute to the preparation and implementation of SRA-hosted conferences and educational workshops by serving on the planning committee, drafting materials, and scheduling potential speakers and panelist as requested.
- Manage activities related to Member Sciences & Regulatory Initiatives (MS&RI) by documenting meeting activities and decisions, proactively identifying and preparing materials and communications, and tracking input from Member companies.
- 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.

- Strong working knowledge of science and regulatory affairs
- Excellent written and oral communication skills
- Exceptional interpersonal skills, a focused listener
- Exhibits a positive attitude and professional demeanor
- Exhibits a high degree of personal initiative and desire to achieve success for AAM
- Exceptional organizational and project management skills for timely implementation of projects involving multiple functions and external resources
- Ability to prioritize and manage multiple initiatives simultaneously
- Ability to work in a collaborative environment and accomplish tasks with self-direction and provide exemplary customer service
- Ability to work creatively and with flexibility in a fast paced environment while maintaining high work standards.
- Fluent computer skills, including basic use of Microsoft Word, Excel and PowerPoint

Education and Experience Requirements:

- Bachelor's Degree, required; science-related field, preferred
- 5+ years of professional experience in FDA role or regulatory experience in a pharmaceutical organization such as manufacturing or quality, required
- Pharmaceutical regulatory experience, required
- Pharmaceutical quality, inspection and investigation experience, required
- Experience with and understanding of the relationship and interconnectivity between various FDA offices that oversee the review and approval of generic drug applications, required
- Experience working with FDA's IT system, preferred
- Project Management experience, required; PMP, desirable

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 10%

This job description does not imply that the stated requirements are the only expectations for the position. Incumbents are expected to perform any other duties that may be assigned. AAM has the right to revise this job description at any time. AAM is an "at will" employer and as such, neither this job description nor your signature constitutes any form of contractual agreement between you and AAM.

Acknowledgement:

Name: _____ Date: _____

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Jobs@accessiblemeds.org