JOB DESCRIPTION

Position Title: Senior Director, Sciences & Regulatory Affairs

Department: Sciences & Regulatory Affairs

Report To: SVP, Sciences & Regulatory Affairs

FLSA: Exempt

Salary Range: $175,000 - $200,000. This position is eligible for health and wellness benefits.

Job Summary: The Senior Director, Sciences & Regulatory Affairs is responsible for advancing AAM's scientific and regulatory initiatives in collaboration with the Science & Regulatory Affairs (Sci Reg) team, members of the Sciences & Regulatory Advisory Working Group (SRAWG), and scientific and regulatory affairs personnel from member companies. This includes the development of AAM's scientific and regulatory policy positions, communications, and member training opportunities. This position is a key member of the team, providing both strategic and operational leadership across all Sci Reg-led initiatives which includes all relative user fee related work. This work also includes AAM's GRx+Biosims conference, the Biosimilars Council, and the International Generic and Biosimilars Association (IGBA). The Senior Director will lead multiple workgroups, task forces, and special projects, as well as cross-functional initiatives in coordination with AAM senior leadership, the Legal department, and other internal teams.

Essential Duties and Responsibilities:

- Serve as the program and project manager on assigned components of Science & Regulatory Affairs (Sci Reg) 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.
- Lead and manage internal and external meetings and activities in support of Sci Reg priorities.
- Represent AAM in assigned external meetings and forums, particularly at FDA, and document proceedings and share with AAM's Sci Reg team.
- Contribute to the preparation and implementation of Sci Reg-hosted conferences and educational workshops by serving on the planning committee, drafting materials, and scheduling potential speakers and panelist as requested.
- Lead and manage public comment opportunities which may include Federal Register notices related to draft FDA guidances, proposed rules, and other opportunities to facilitate and reflect members current thinking.
- Lead and manage periodic communications to membership workgroups and taskforces.
- Lead and manage user fee related meetings which may be related to negotiations or implementation of user fee commitments.
- Lead and manage Sci-Reg initiatives as it relates external partners and stakeholders

- Develop and implement process improvement opportunities for the Sci Reg department
- Perform other duties as assigned in alignment and 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 and active listener
- Exhibits a positive attitude and professional demeanor
- Exhibits a high degree of personal initiative and desire to achieve success for AAM
- Strong working knowledge of the FDA and other global health authorities
- Strong working knowledge of user fee programs and the impact of how user fee agreements impact generics, biosimilars, and other modalities as needed
- 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
- 8+ years of professional experience in FDA role or regulatory experience in a pharmaceutical organization such as manufacturing or quality, required
- Program and Project Management experience, required

Travel: up to 10%