JOB DESCRIPTION

Position Title: Senior Director, Sciences & Regulatory Affairs

Department: Sciences & Regulatory Affairs

Report To: Senior Vice President, Sciences & Regulatory Affairs

FLSA: Exempt

Last Revision Date: 2019 07 10

Job Summary: The Senior Director, Sciences & Regulatory Affairs, in partnership with the SVP, Sciences & Regulatory Affairs and other members of the Sciences & Regulatory Affairs Team, is responsible for the development and oversight of the Association for Accessible Medicines' (AAM) Science & Regulatory Affairs (SRA) initiatives. Initiatives will be achieved by working with members of the Sciences and Regulatory Advisory Working Group (SRAWG), other Science & Regulatory Affairs personnel from member-companies, AAM SRA staff, and staff across all AAM functional groups. The role is also responsible for member communications and training opportunities for SRA initiatives.

Essential Duties and Responsibilities:

- Lead assigned working groups to achieve identified objectives through efforts of member company representatives, AAM staff, consultants, and agency staff.
- Maintain relationships with key personnel at FDA and USP on behalf of AAM.
- Manage activities across multiple SRA working groups and initiatives as appropriate to maximize impact; oversee activities of other SRA staff as necessary.
- Manage activities of SRA across all AAM functional groups as assigned and required.
- Manage the preparation and implementation of SRA-hosted conferences and education workshops. Responsibilities include but are not limited to:
  - Managing the preparation of all materials, advance and meeting-specific.
  - Leading planning committees as assigned, ensuring member-company, FDA, USP, and other relevant stakeholders input.
  - Working with panelists and speakers to ensure message points, resolve questions and assure an effective event.

- In collaboration with the VP, Sciences & Regulatory Affairs, contribute to the management of Member Sciences & Regulatory Initiative (MS&RI). Duties include but are not limited to collecting requests and recommendations from members for issues and projects, facilitating discussion and actions between member-companies and FDA.
- 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.

- Advanced knowledge of the regulatory process and regulatory issues of the generic pharmaceutical industry.
- Ability to be diplomatic, resourceful and persuasive.
- Exceptional organizational and project management skills to lead working groups for timely implementation of projects involving multiple functions and external resources.
- 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 demonstrate business-savvy judgement.
- Ability to take responsibility for assignments 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 oral communication skills.
- 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:

- Bachelor's degree in science-related field required, Advanced degree in science preferred.
- 8+ years of experience in pharmaceutical science related role, with 5+ years in government regulatory agency (FDA) and/or a pharmaceutical industry regulatory department required.
- Experience with ANDA dossier development and filing preferred.
- Project management experience and/or supervisory experience required.

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% domestic travel

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: _____

www.accessiblemeds.org