**JOB DESCRIPTION:**

Responsible for global regulatory affairs strategy for assigned projects covering the development, registration and post approval phases, and acts as liaison with the health authorities including the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) review divisions and Office of Prescription Drug Promotion (OPDP), European Medicines Agency (EMA), and national authorities. Works closely with other functional areas to develop regulatory strategies and timelines, including regulatory operations, project management, translational sciences, clinical development, pharmacovigilance, legal, marketing, sales operations, and medical affairs.

**ESSENTIAL DUTIES & RESPONSIBILITIES:**

- Actively participates on product strategy teams and provides advice and direction including identifying and assessing regulatory risks regarding regulatory requirements and strategies.
- Develops and executes effective proactive regulatory strategies and plans.
- Ability to support the product strategy team to assess whether technical arguments are presented clearly and conclusions are supported by data and their associated risk assessments.
- Support U.S. post-marketing activities for commercial products, including review and approval of commercial labeling and advertising/promotional materials.
- Provide interpretive analyses of complex regulatory guidance documents, regulations, or directives that impact the Company’s development programs. Advise personnel in other departments regarding their applicability and impact.
- Perform regulatory intelligence activities to keep current on the regulatory environment and competitive products; communicate such environment to the teams.
- Reviews documents and work closely with Regulatory Operations to publish the final regulatory submissions to FDA CDER review divisions, OPDP and as EMA and national authorities.
- Primary contact for assigned projects with key personnel in FDA CDER review divisions, OPDP and as EMA and national authorities for assigned projects.
- Develops proposed product labeling working with Marketing, CMC, Clinical Development, Nonclinical Development and Pharmaceutical Development.
- Plans, coordinates and leads meetings with Regulatory Authorities (e.g., Pre-IND, End of Phase 2, Pre-NDA, Scientific Advice and national advice) including meeting requests, meeting background documents and action plan following such meetings.
- Works with Project Management, Medical and Regulatory Communications and relevant disciplines on planning summaries for marketing applications.
- Participates in the planning and review of all regulatory submissions with the Information and Submission Management function.
- Participates in the development of Regulatory Affairs department SOPs.
- Establishing standards for compliance of regulatory submissions with health authority laws, regulations and guidance documents.
- Maintains knowledge of the laws, regulations and guidelines governing drug development and approval.
- Manages and reviews safety reports and submissions.
REQUIREMENTS:

- Bachelor’s and/or Master’s degree in scientific, health care or related field or equivalent.
- A minimum of 10 years of pharmaceutical industry experience, with 5+ years of regulatory experience.
- Previous management experience is preferred. Must demonstrate the ability to work through others.
- Must demonstrate understanding of drug development and knowledge of FDA requirements. Working knowledge of scientific principles.
- Direct experience with OPDP and marketed products preferred.
- Direct experience with FDA required and international experience preferred.
- A leadership role on project teams with approximately 40% of time in meetings.
- Highly organized with attention to detail. Strong verbal and written communication skills are required, as well as excellent scientific writing, presentation and documentation skills.
- Has familiarity with MS Word, MS Excel, Adobe Acrobat and PowerPoint applications. Working knowledge of electronic publishing/file management system.
- Moderate travel (approximately 10-20%)

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.

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