

## **Job Description**

### **Senior Regulatory Affairs Manager**

**Job Description:** The Regulatory Affairs Manager is the primary point of contact and is responsible for facilitating integrated delivery, oversight, and management of all phases of IND life cycle. The goal is to ensure optimal IND or BLA preparation, including overseeing project scope, managing process with multiple function teams, and meeting key timelines and milestones.

**Level of Position:** Flexible based on the candidate experience

#### **KEY DUTIES AND RESPONSIBILITIES:**

- Representing the company in formal meetings with the FDA and EMA
- Overall project management from project kick-off through IND or BLA preparation/other regulatory submission for FDA, ensuring that the project objectives have been met
  - Direct IND and NDA coordination and preparation
  - Edit regulatory document, and ensure compliance with FDA regulations guideline for Good Clinical Practice (ICH-GCP), and Standard Operating Procedures (SOPs) for projects filed under a U.S. Investigational New Drug (IND), BLA, or other FDA requirements
  - Communicate effectively with internal and external members of senior management, the project team, investigators and site personnel, and expert physicians
  - Lead the development, implementation and review of the Project-Specific Plans
  - Manage problem identification and resolution in order to adhere to the project timelines and budget
  - Recommend outsourcing when appropriate and interact with appropriate project team members to ensure that outsourcing to Contract Research Organizations (CROs)/vendors will meet expected performance standards for quality, timeliness and budget
  - Supervise the planning and facilitation of investigator meetings
  - Participate in bid defense presentations and meetings
  - Collaborate interdepartmentally on the proposal development process
  - Other duties as assigned

#### **REQUIRED EDUCATION AND EXPERIENCE**

- Bachelor's degree (or equivalent) in life science, biological science, clinical research or any other healthcare field and 5 years of experience with regulatory affairs in pharmaceutical or biotechnology firm.

OR

Advanced degree (MS, MD, PharmD, PhD, etc.) in life science discipline, biological science, clinical research or any other healthcare field and 3 years of experience with regulatory affairs pharmaceutical or biotechnology firm

- Working knowledge of FDA regulatory requirements for IND and BLA.
- Extensive understanding of eCTD modules, regulations, clinical research principles and drug development processes
- Ability to write regulatory modules in eCTD system, and to manage overall project scope and timelines using appropriate skills (e.g. need be familiar with Gantt plots for PM)
- Ability to drive projects to completion by proactively coordinating the efforts of external and internal partners or CROs
- Strong written and verbal communication skills
- Dynamic individual with ability to lead, organize and motivate team members
- Ability to work effectively both independently and in a team environment
- Strong organizational and planning skills
- Excellent interpersonal and professional skills
- Excellent time management skills with the ability to prioritize responsibilities and multitask
- Self-motivated and detail oriented
- Proficient in Microsoft Office and able to learn appropriate software