100 High Street, 28th Floor, Boston MA 02110 USA

Position Title:	Manager, Regulatory Affairs
Department:	Regulatory Affairs
Hiring Manager:	SVP, Regulatory Affairs & Quality Assurance
Date Opened:	October 2020

We are a team of experts from multiple disciplines who have come together driven to bring hope and life-changing therapies to patients and their families.

Position Overview:

Reporting to the Senior Vice President of Regulatory Affairs and Quality Assurance, the successful candidate will be responsible for supporting the regulatory function and its activities through preparation of high-quality regulatory submissions and contribution to global regulatory strategies. The ideal candidate will represent regulatory on cross functional teams as well as prepare and submit packages to the FDA and other regulatory authorities for filings and approval of programs.

Responsibilities:

- Reviews and approves regulatory submissions (i.e. NDAs, IND amendments, annual reports, etc.) to the Food and Drug Administration (FDA) and other regulatory authorities to ensure compliance with applicable regulations and guidance.
- Supports the preparation of regulatory documentation and submission activities to meet critical business objectives.
- Creates submission plans and manage timelines and document workflow from draft through finalization for submissions.
- Prepares both routine and complex submissions in compliance with department and regulatory requirements and guidelines.
- Works with team members to identify resource requirements and strategies to address overlapping resource demands and rate limiting factors.
- Identifies and manages issues and opportunities that impact submissions timelines; ensures appropriate communication, resolution and/or escalation as needed.
- Ensures regulatory plans are monitored, progress/variance communicated, and any risks are highlighted.
- Collaborates within regulatory and cross-functional colleagues on the preparation and submission of regulatory filings, including major marketing applications.
- Prepares and reviews sections of regulatory submissions for IND/CTA original submissions and amendments, orphan designations, and pediatric investigation plans.
- Participates in regulatory intelligence research activities, as needed.
- Interacts with various departments as needed on regulatory issues and/or strategy. Effectively guides, communicates and implements determined strategy with the appropriate departments and/or employees.
- Implements policies to assure on-going compliance of Regulatory Affairs activities.
- Assesses impact of new regulations and suggests appropriate changes to business processes/policies as necessary.
- Interacts with the FDA and other regulatory authorities to facilitate approval of the regulatory submissions.
- Maintains awareness of all regulatory activities on assigned projects. Works to minimize regulatory issues and helps prevent unnecessary regulatory delays.

Qualifications:

- Bachelor's Degree and 5+ years of experience in life sciences, biotech, pharma regulatory or closely related field. Advanced degree preferred.
- Established working knowledge of regulatory guidelines and regulations, US and international
- Direct experience leading regulatory aspects of IND/CTA/NDA/MAA submissions, experience with small molecules strongly preferred
- Demonstrated evidence of writing Regulatory portions of high-quality regulatory documents
- Detail oriented with excellent oral and written communication skills, including proficiency in scientific writing, and experience interfacing with management
- Strong organizational skills and ability to maintain a high level of communication, productivity, innovation, and priority-setting to work effectively in a dynamic environment to meet aggressive timelines
- Self-motivated, self-disciplined, and able to function independently as well as part of a team
- Strategic agility, strong critical and logical thinking with the ability to analyze and propose solutions to problems
- Excellent computer proficiency (MS Word, StartingPoint, Excel, PowerPoint, Adobe Acrobat)