

Director, Regulatory Affairs

OVERVIEW

We are currently seeking a Full Time US Director of Regulatory Affairs to support our Regulatory Affairs team under the direction of our Global Sr. Director, Regulatory Affairs.

The primary purpose of this position is to lead our US Regulatory Affairs team and to ensure compliance with regulatory requirements.

YOUR MISSION

- The main responsibilities of this position will include but are not limited to the following tasks:
- Leads Regulatory Operations in the US and develops and improves regulatory processes
- Leads and develops the US Regulatory Affairs team
- Develops regulatory strategies and implementation plans and feeds into cross functional project teams
- Ensures compliance with regulatory requirements and adhere to internal corporate policies and operating processes.
- Provides timely and clear updates on project timelines, deliverables, and issues.
- Works with multiple stakeholders in cross functional teams.
- Ensures production of high-quality regulatory submission documents.
- Develops and maintains regulatory document archiving and tracking databases.
- Develops and maintains regulatory knowledge of regulations and guidelines.
- Contributes in review and authoring of SOPs.

YOUR PROFILE

The qualifications for this position include, but are not limited to the following:

- REQUIRED: Bachelor's Degree. Degree in Science is strongly preferred.
- A minimum of ten (10) years of experience in Regulatory Affairs with 5 years of management experience.
- Experience with biologicals and/or gene & cell therapy in oncological indications is a plus.
- Strong knowledge of FDA regulations and GxP quality guidelines.
- Experience with CTD and document management systems.
- Experience with clinical trial registries.
- Strong leadership and team building skills.
- Strong coordination and problem solution abilities.
- Manages issues proactively, manage conflicts, and mitigate regulatory risk.
- Good organization and time management skills.
- Strong oral and written communication skills.

Competitive Total Rewards package

- Base Salary
- Annual Bonus
- Stock Options – based on position level
- 401K plan with company match
- Generous Holiday Time
- Generous Paid Time Off (PTO) for ALL EMPLOYEES regardless of position level
- Full Benefits
- Health Insurance
- Dental/Vision insurance
- Short-Term and Long-Term Disability
- Other voluntary insurance (Pet, Legal Shield Identity Theft Protection, Travel Assistant, Accidental Injury and Critical Illness,)
- Family Medical Leave
- Parental Leave
- Employee Assistance Program
- Life Insurance policy
- Additional Voluntary Life Insurance
- Personal time with the CEO in your first 30 days
- Collaborative and family environment
- Monthly Site meetings with fun team building events
- Themed Holiday party
- Social Community Outreach participation
- Development training and planning
- Various committees to foster collaboration and involvement within the company
- Hybrid work schedules (based on position need and supervisor's approval)