REDEPLOYMENT

DIRECTOR, REGULATORY AFFAIRS

POSITION: Director of Regulatory Affairs
LOCATION: San Diego, CA; Full Time, On-Site

We have been hired to identify a Director of Regulatory Affairs at a Clinical Stage Immuno-Oncology company that is completely changing the utilization of oncolytic virus delivery through an allogeneic cell-based delivery system. This novel technology is combining stem cells with an oncolytic virus for use in oncology indications.

The role of the Director of Regulatory Affairs entails providing strategic leadership in ensuring regulatory compliance. This position holds the responsibility for formulating, evolving, and executing regulatory strategies while overseeing worldwide regulatory submissions. The Director will act as the central liaison with global regulatory bodies, assuming accountability for all regulatory submissions, tasks, and correspondence on a global scale.

ROLES AND RESPOSIBILITIES:

- Spearheads the preparation and submission of regulatory filings, encompassing investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), and various other regulatory submissions.
- Supervises the creation, assessment, and submission of regulatory documents, including comprehensive briefing packages, annual reports, safety updates, and responses to inquiries from regulatory agencies.
- Monitors and guarantees adherence to all pertinent regulatory prerequisites, encompassing FDA, EMA, and other relevant guidelines, ensuring full compliance.
- Takes charge of regulatory initiatives across the company's diverse portfolio, crafting and executing innovative global regulatory strategies, often in unprecedented scenarios.
- Establishes and cultivates impactful professional relationships with FDA and global health authorities, skillfully facilitating, negotiating, and resolving matters as required.
- Proactively seeks opportunities to secure FastTrack, orphan drug designation, Breakthrough Therapy, and Prime designation for pipeline products.
- Collaborates closely with Research and Development, Clinical Development, Quality Assurance, Manufacturing, and other pertinent departments to seamlessly integrate regulatory prerequisites into product development plans and procedures.
- Identifies potential risks related to programs or submissions and implements pertinent regulatory mitigation strategies to ensure successful outcomes.
- Guides the orchestration of regulatory meeting packages and contributes substantively to engagements with Regulatory Authorities.
- Partners with and supports clinical development, CMC, non-clinical, quality, medical affairs, and commercial functions, playing a pivotal role in the assessment and submission of clinical protocols, regulatory documents, publications, and investor relations/legal public disclosures across the product life cycle.

- Prepares the organization comprehensively for regulatory audits and inspections, ensuring preparedness, coordinating inspections, and effectively addressing findings.
- Provides regulatory oversight for program documents, encompassing target product profiles, development plans, and non-clinical and clinical protocols and reports.
- Develops standardized regulatory procedures spanning from preclinical stages to commercialization, establishing a uniform framework.
- Assembles an internal team as necessary over time, assuming responsibility for all dimensions of regulatory affairs, spanning regulatory strategy, non-clinical, regulatory CMC, regulatory intelligence, and regulatory operations, leveraging external consultants and outsourcing vendors when appropriate.
- Offers vigilant oversight and management of external regulatory vendors and resources.
- Provides expert guidance on labeling, promotional review, and post-marketing/commercial regulatory endeavors.
- Instigates and/or contributes to process enhancements that hold significance for Regulatory Affairs or other interconnected departments.
- Represents the Company's interests in interactions with national government agencies, industry associations, and other bodies that shape legislative, regulatory, and guideline landscapes.
- Executes additional responsibilities as assigned.

EDUCATION AND EXPERIENCE REQUIRED:

- **Required**: Bachelor's Degree;
    - **Preferred:** Advanced Degree (Master's or Ph.D.), with a focus on Life/Health Sciences.
- A minimum of **8-10 years** of experience in the pharmaceutical/biotech sector.
- **4-6 years** of managerial experience within Regulatory.
- Demonstrates familiarity with current US and international regulations and guidelines, with a history of directing Regulatory efforts in global contexts.
- Exhibits prior regulatory leadership in projects spanning pre-clinical to clinical phase 3 studies.
- Understanding of FDA regulations and guidelines for drug development.
- Proven experience in preparing and managing IND applications, and ideally, leading NDA preparation and negotiation toward marketing approval.
- Regulatory project management expertise, encompassing interaction, negotiation, and meetings with the FDA, along with proficiency in crafting IND/CTA and NDA/MAA submissions.
- Brings valuable experience in small startup environments.
- Exposure to Cell and Gene therapy realms.
- Holds experience interfacing with and responding to pertinent global regulatory authorities.
- Proficiency in handling mathematical concepts, including tasks like calculating dilutions and performing statistical analyses.
- Application of mathematical concepts such as fractions, percentages, ratios, and proportions to real-world scenarios.

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BENEFITS:

- Salary: $200K - $250K
- Competitive Total Rewards package (100% premium payment for employee coverage for medical, dental, and vision. 4% 401k Safe Harbor match)
- General stock option plan
- Weekly onsite meals, daily snacks and beverages
- Team building activities

Redeployment is defined as "the process of moving people to a different place or using them in a more effective way." We are a recruiting and executive search firm that uses our size and unique background to provide a personalized hiring experience to startups as they raise money, expand their business, and grow their team. With a focus in the biotech space, our expertise is getting to know and understand company culture, ensuring the RIGHT prospects are connected to the RIGHT companies!

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