Job Title: Executive Director / Vice President, Regulatory Affairs

Location: Remote – US / Europe

Reports To: Chief Medical Officer (CMO)

Job Overview:

Ottimo Pharma is seeking an experienced **Executive Director / Vice President, Regulatory Affairs** to lead the regulatory strategy and operations for our innovative oncology pipeline. This executive will be responsible for defining and executing regulatory pathways, ensuring compliance with global regulatory authorities, and driving the overall regulatory strategy to accelerate development and approval of novel cancer therapies. The ideal candidate will bring deep expertise in regulatory affairs, oncology drug development, and experience working in a fast-paced, entrepreneurial environment. The company is preparing to file its first Investigational New Drug (IND) application, making this a pivotal role in shaping regulatory milestones and clinical development.

Key Responsibilities:

Strategic Leadership:

- Define and drive the overall regulatory vision and strategy to support oncology drug development.
- Provide leadership in aligning regulatory strategies with corporate goals and business objectives.
- Ensure regulatory compliance while fostering an innovative and agile approach to drug development.

Strategy & Implementation:

- Develop and implement global regulatory strategies for oncology programs from preclinical development through commercialization.
- Lead the preparation and submission of the company's first IND application, ensuring compliance with FDA and other regulatory agency requirements.

- Oversee the preparation, submission, and maintenance of regulatory filings, ensuring adherence to evolving regulatory requirements.
- Provide strategic guidance on regulatory requirements, including IND/CTA submissions, breakthrough therapy designations, accelerated pathways.

Cross-Functional and External Collaboration:

- Serve as the primary liaison with regulatory agencies (FDA, EMA, and other global authorities), leading all interactions, meetings, and submissions.
- Partner cross-functionally with R&D, clinical, CM teams and external consultants to integrate regulatory strategy into overall program development.
- Stay abreast of changes in the global regulatory environment and proactively adapt regulatory strategies accordingly.

Qualifications & Experience:

- Advanced degree (PhD, PharmD, or MSc) in life sciences, regulatory affairs, or a related field.
- 15+ years of regulatory affairs experience, with a strong track record in oncology drug development.
- Proven leadership in developing and executing global regulatory strategies in a biotech or pharmaceutical setting.
- Direct experience interacting with FDA, EMA, and other regulatory authorities, including leading successful submissions and approvals.
- Expertise in regulatory requirements for oncology especially with biologics. Previous experience in immune-oncology field
- Strong understanding of expedited regulatory pathways (e.g., Fast Track, Breakthrough Therapy, Orphan Drug, RMAT).
- Experience leading IND submissions and early-phase clinical development strategies.
- Excellent strategic, analytical, and problem-solving skills.

- Ability to thrive in a fast-paced, dynamic startup environment and influence stakeholders across all levels.

To apply for this opportunity please send your resume via email to careers@ottimopharma.com. Please include the position title in the subject line.

Ottimo Pharma is an equal opportunity employer and is committed to creating an inclusive environment for all employees. We celebrate diversity and do not discriminate based on race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, veteran status, or any other protected status under applicable laws.