About Tevogen Bio

We are a clinical-stage specialty immunotherapy company harnessing the power of CD8+ cytotoxic T lymphocytes ("CD8+ CTLs"), one of nature's most powerful immunological weapons, to develop off-the-shelf, precision T cell therapies for the treatment of infectious diseases, cancers, and neurological disorders with the aim of addressing the significant unmet needs of large patient populations.

We believe that personalized immunotherapies which are accessible to the masses are the next frontier of medicine, and a disruptive business model is necessary to increase the pace of medical innovation. Core to the company's successful biopharma business model is its culture of Creativity, Optimism, Respect, Equality, and keen focus on organizational and manufacturing efficiency.

Job Description

Job Title: Regulatory Affairs Lead
Work Location: Tevogen R&D Center, Philadelphia PA 19107
Division/Department: Research and Development
Reports to: Chief Scientific Officer
Position: Full-time, Exempt

Essential Duties and Responsibilities:

As the Regulatory Affairs Lead you will support Tevogen's R&D Division by:

- Owning the company's regulatory function providing direction and implementation for the lead and follow on programs including pivotal trial design input, BLA meetings, labeling.
- Preparing for BLA/FDA regulatory and all submission types, and potentially other health authority discussions/meetings.
- Anticipating long-term regulatory strategy for the pipeline, preparing for potential roadblocks, mitigating risks, and critically thinking about regulatory agency requirements.
- Spearheading cross-functional dialogues with relevant partnerships across internal departments and external stakeholders.
- Ensuring project team colleagues, line management, and key stakeholders are apprised of developments that may impact regulatory success, exercising sound judgement and communicating in a professional and timely manner.
- Proactively anticipating risks and responsible for developing solutions to identified risks and discussing with team and management; understands probabilities of technical success for the solutions.
- Serving as direct point of contact with health authorities, leads and managing FDA meetings.
- Where applicable, hiring and overseeing vendor responsibility for regulatory activities and submissions related to projects within scope.
- Potentially serving as lead regulatory reviewer in due diligence for licensing or other opportunities.
- Monitoring and anticipating trends impacting the regulatory and access environments to strengthen product development plan(s) and adopt regulatory strategies promptly.

Education and/or Work Experience Requirements:

- Minimum of a bachelor's degree. Advanced degree, such as MS, MD, PharmD, or PhD highly preferred.
- Minimum of 8+ years of regulatory experience in the biotech industry, preferably on the sponsor side.
- Demonstrated expertise in the regulatory strategy for biologics development, particularly cell therapies, with a history of successful BLA filings.
- Deep understanding of the relationship between clinical trial design and product labels.
- Comprehensive knowledge of the regulatory process across all stages of drug development, from pre-IND through to post-approval.
- Understanding of the regulatory framework for the clinical development and manufacturing of cell and gene therapy products leading to global marketing authorizations.
- Ability to interpret and advise on applicable regulations and guidance documents, reflecting the experience gained in the field.
- Proven experience in authoring, reviewing, and managing components of IND and BLA dossier submissions.
- Strong background in negotiation with FDA and global health authorities and managing clinical trial applications in major geographies around the world.
- Understanding of the regulatory framework for the clinical development and manufacturing of cell and gene therapy products leading to global marketing authorizations.
- Knowledge of FDA, EU, and other key markets, with post-marketing experience being a plus.
- Excellent oral and written communication skills, with a proven ability to manage timelines, negotiate effectively, and adapt to changing circumstances.
- Tenured experience in regulatory strategy, including understanding and applying broad regulatory concepts with global implications.
- Excels at building and managing relationships across teams and geographic locations, both internally and externally.

Travel Requirements:

This position currently requires onsite work in New Jersey. The role may require occasional travel to Tevogen's Warren, NJ HQ.

We are an equal opportunity employer. All applicants will be considered for employment without attention to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran, or disability status.

Prospective new hires for this position must be fully vaccinated against COVID-19 as a condition of employment. Vaccine verification will be required on your start date unless an exemption has been approved by the Company as a medical or religious accommodation.

Tevogen Bio Plans to Become Publicly Listed on NYSE via Business Combination with Semper Paratus Acquisition Corporation. Learn more here: *https://www.globenewswire.com/news-release/2023/06/29/2696959/0/en/Tevogen-Bio-to-Become-Publicly-Listed-on-NYSE-via-Business-Combination-with-Semper-Paratus-Acquisition-Corporation.html*