About Tevogen Bio

Tevogen Bio Inc. is a late-stage clinical biotechnology company with a rapidly advancing diversified product pipeline and broad research portfolio. The research pipeline includes off-the-shelf, allogeneic genetically unmodified precision CD8+ T Lymphocyte therapeutics for the treatment of common cancers, neurologic diseases, and difficult to eradicate serious viral infections.

Tevogen leadership believes 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 company's successful biopharma business model is its culture of Creativity, Optimism, Respect, Equality, and keen focus on continuous process improvement as well as organizational and manufacturing efficiency. Tevogen is rapidly expanding its R&D, Technical Operations and Commercial Teams.

Job Description

Job Title: Regulatory Affairs Manager
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:

The Regulatory Affairs Manager is responsible for support regulatory activities related to product development, ongoing clinical trials, quality assurance, and data reporting for post-marketing studies. Specific functions include:

- Provide FDA compliant regulatory support and consultation in the development of new protocol submissions:
    - Collaborate with and advise R&D personnel in the formulation of new Investigational Drug Exemption (IND) applications required to conduct new protocols.
        - Specific areas of guidance in new IND applications and clinical trials include, but are not limited to, interpretation and adaptation of FDA guidance in product manufacturing, labeling, adventitious testing, storage and transport, clinical trial adverse event reporting to the FDA and to local IRBs, safety considerations of proposed clinical trials, and safety monitoring plan.
    - Manage the submission of all regulatory documents required for new IND submission.
    - Arrange, conduct, and follow up on all meetings with the FDA as needed for new product development.
    - Provide support for the timely preparation, editing and review of submissions, including regulatory agency Meeting Requests and Briefing Documents, IND/CTA amendments, original Marketing Authorization Applications, and their respective amendments/supplements. Advise and collaborate with clinical trial sites on regulatory requirements.
    - Assist in the education of personnel from Clinical Research Organizations (CRO) regarding regulatory requirements for new studies.
    - Participate in the development of the product pipeline.
- Provide FDA compliant regulatory support and consultation in the conduct of ongoing clinical trials:

  - Respond to inquiries from regulatory authorities, including the FDA
  - Prepare and compile abbreviated new drug applications (ANDA), Amendments, Supplements, Annual Reports, 502(b)(2) and 505(b)(1) filings, ensuring that they comply with applicable regulatory guidelines and that the highest standards are met.
  - Provide regulatory expertise to CROs and clinical trial sites in preparing institutional and FDA required reports
  - Critically review documentation intended for submission to the FDA for consistency relevant to FDA guidelines
  - Remain informed of new or updated guidance from the FDA and assess the impact to planned and ongoing Tevogen clinical trials and drug manufacturing
- Assist in the development and data reporting of post-marketing studies as required by the FDA
- Manage the quality, accuracy, compliance with internal and external standards, and the timely production of submission documents using manual and electronic document management systems, as appropriate.
- Collaborate with the Chief Scientific Officer and the Chief Technological Officer in implementing a set of laboratory and clinical processes and controls that all data collected during manufacturing, clinical trials, and research is accurate, complete, consistent, and current
- Collaborate and engage with affiliated CROs regarding ongoing monitoring of data accuracy, data extraction accuracy, compliance with collected clinical trial data
- Assure the accurate and timely reporting of adverse events to the FDA

Education and/or Work Experience Requirements:

- Excellent verbal and written communication skills, including ability to effectively communicate with internal and external colleagues
- Strong time and project management skills with attention to detail and the ability to plan and prioritize work and balance multiple projects
- Working knowledge of US and global regulatory requirements for pharmaceutical and biologics products
- Knowledgeable in industry trends for regulatory affairs
- Excellent computer proficiency (MS Office – Word, Excel, Powerpoint, and Outlook)
- Self-organizing, self-directing, highly motivated with strong critical thinking and analytical skills.
- Minimum of 7 years in the pharmaceutical industry
- Minimum of 5 years of experience in regulatory affairs
- Bachelor’s degree required; master’s degree preferred.

Physical Requirements:

- Ability to safely and successfully perform the essential job functions consistent with the ADA, FMLA and other federal, state and local standards, including meeting qualitative and/or quantitative productivity standards.
- Ability to maintain regular, punctual attendance consistent with the ADA, FMLA and other federal, state and local standards.
- Rare travel to main company headquarters.

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.

We maintain a drug-free workplace and perform pre-employment substance abuse testing.