Job Description

Assoc. Director of Stability and Reference Standard

Vaxcyte, Inc.

November 2020

Company Profile:

Vaxcyte, Inc. (Nasdaq: PCVX) is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent some of the most common and deadly infectious diseases worldwide. Our exclusively licensed cell-free protein synthesis platform and our proprietary know how enable us to design and produce optimized protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies cannot. Our pipeline includes pneumococcal conjugate vaccine, or PCV, candidates that we believe are the most broad-spectrum PCV candidates currently in development, targeting the $7 billion global pneumococcal vaccine market. Our lead vaccine candidate, VAX-24, is a preclinical, 24-valent broad-spectrum pneumococcal conjugate PCV with preclinical proof-of-concept demonstrating potential to replace the standard of care that we expect to advance into clinical trials in the second half of 2021. Our pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 30 strains, including newly emerging strains responsible for invasive pneumococcal disease and antibiotic resistance; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease by targeting the keystone pathogen responsible for this chronic, oral inflammatory disease. We completed our initial public offering in June 2020, raising $287.5 million in gross proceeds.

Summary:

Vaxcyte is looking for an energetic and talented individual to join Vaxcyte's Vaccine Product Development organization as an Associate Director within Analytical Development. The primary function of this director level position is to lead the stability and reference standard program for all products in preclinical and clinical development. This position reports directly to the Senior Director of Analytical Development and QC (AD & QC). The successful candidate will also provide leadership and CMG compliance guidance for junior colleagues in AD & QC department.

Essential Functions:

- Lead Vaxcyte's stability and reference standard program for all development phase conjugated vaccine projects.
- Take on end-to-end responsibility of stability and reference standard program for critical raw material, intermediates, and drug substance and drug products.
- Independently formulate phase appropriate, risk and science based stability and reference program strategy, and gain cross-functional alignment on the strategies
- Design stability studies and reference standard qualification studies to implement the project's overall stability and reference standard strategy.
- Oversee stability studies carried out internally or at our CMOs This will include R&D stability studies to support process development, toxicology nonclinical studies, or GMP stability studies for clinical products.
- Author or review and approve all stability study protocols and reports.
- Review and approve all stability study data, deviations, and investigation reports.
- Responsible for stability data trending, use statistical tools if necessary
- Responsible for setting product expiry based on the stability data analysis and trending

- Collaborate with process development and analytical development scientist, QC at CMOs for stability investigation
- Supervise scientists, associates and stability contract sites for implementation of stability protocols. Ensure that stability protocol is executed correctly, all stability acitivities are adequately documented, and stability equipment are qualified, maintained and monitored
- Collaborate with Formulation, Process Development, Conjugation, and CDMOs/CROs for stability study design, execution, and expiry labeling.
- May author multiple regulatory submission and address health authority questions for IND approval
- Support QA organization by evaluating and performing technical audit of potential CMOs/CTLs for method development, testing or stability studies
- Evaluate and establish contracts with CDMO/CROs for method development, testing or stability studies
- Manage relationships with existing and new CDMOs, including managing timelines and cost for the stability studies and reference standards.

Requirements:

- MS or BS in Chemistry, Analytical Chemistry, Organic or Biochemistry, with 15+ years of industry experience in Pharma / Biotech industry required
- Solid understanding of relevant FDA, EU, and ICH regulatory guidelines and pharmacopeia as applicable to stability study design, expiry dating, reference standard qualification and dating, and analytical method qualification/validation for small molecules, biologics and vaccines, and demonstrated ability of applying the regulatory guidance to formulate practical solutions and phase appropriate analytical strategy
- Ideal candidate will have successful track record of heading company's stability and reference standard program with the end to end responsibilities.
- Strong understanding of various analytical chemistry methodology principles, and track record of validation for GMP release and stability testing, and stability trouble shooting
- Solid understanding and hands-on experience of applying basic statistical tools for stability data trending and rate analysis to support retest period/shelf life proposals is preferred
- Experience in IND, NDA and BLA submission is highly preferred
- Experience working in a regulated (GLP / GMP) environment
- Attention to detail and excellent skills in record keeping / documentation
- Extensive technical writing experience
- Project management skills including the ability to manage one's project resource requirements (material, manpower, time, etc.), and ability to elevate relevant issues to project lead and line-management
- Strong interpersonal skills; ability to communicate effectively both verbally and in written formats
- Self-starter; ability to work in a fast-paced, cross-functional environment and collaborate effectively with other team members

Reports to: Senior Director, Analytical Development & Quality Control

Location: Foster City, CA

Compensation: The compensation package will be competitive and includes comprehensive benefits and an equity component.

Send resumes to: careers@vaxcyte.com

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