Job Description

Director / Assoc. Director, Analytical Development for QC

Vaxcyte, Inc.

October 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 / Director within Analytical Development Quality Control department. The primary function of this Director level position in to lead the analytical development 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 scientific mentorship and technical guidance for junior colleagues in analytical development.

Essential Functions:

- Provide strategic, tactical and technical leadership for Analytical Development and QC
- Take on end-to-end strategic responsibility for analytical method development of intermediates, drug substance and drug products.
- Direct method development for quality control and stability testing of proteins, bacterial polysaccharides, and polysaccharide-protein conjugates, and adjuvanted vaccines (vaccines or biologics experience not required)
- Take on end-to-end responsibility of method development for GMP lot release and stability testing of proteins, bacterial polysaccharides, polysaccharide-protein conjugates, and adjuvanted vaccines product. Responsibility also includes resource planning, team productivity and timeline management of the deliverables.
- Drive analytical innovation and stay on top of cutting edge analytical technology. Introduce and establish novel technology in house if necessary.
- Manage scientists of various levels, provide technical direction, mentorship and coaching
- Cultivate a cohesive, innovative, nimble and productive team environment

- Support Associate Director of QC for GMP analytical method transfer and validation at the CMOs, as well as trouble shooting of QC testing or method related issue
- Design stability studies of critical material, intermediates, and drug substance and drug product of company's conjugate vaccine projects. This will include R&D stability studies to support process development, toxicology nonclinical studies, or GMP clinical studies.
- Support stability team on data trending, and stability investigation
- Collaborate with Formulation, Process Development and Conjugation to design and develop phase appropriate analytical methods for in-process control and GMP quality control purpose.
- Author multiple regulatory submission and address health authority questions during various clinical phases
- Evaluate and establish contracts with CDMO/CROs for method development and GMP testing or stability studies
- Manage relationships with CDMOs, including managing timelines and cost for the analytical method and GMP testing.
- Provide appropriate CRO/CDMO oversight by reviewing analytical method development data, reviewing and approving analytical method development report, method validation protocols, reports, and analytical method SOPs

Requirements:

- PhD in Chemistry, Analytical Chemistry, Organic or Biochemistry, with 10+ years relevant industry experience; MS or BS with 15+ years of industry experience in Pharma / Biotech industry required
- Ideal candidate will have proven track record of analytical development for biologics, carbohydrate and conjugates, as well as developing stability strategy for pharmaceutical product in the development phase
- Strong understanding of various analytical chemistry methodology principles and successful track record of method development, trouble shooting and validation for GMP release and stability testing.
- Proven track record of developing polysaccharide, small molecules, protein and conjugate assay methodologies such as content method, purity/impurity method by H/UPLC, capillary electrophoresis, SEC, CEX, icIEF is a must.
- Must possess strong troubleshooting skills under GMP environment
- Solid understanding of relevant FDA, EU, and ICH regulatory guidelines and pharmacopeia as applicable to stability study design, expiry 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
- Experience in IND, NDA and BLA submission is highly preferred
- Project management skills including the ability to manage project resource requirements (material, manpower, time, etc.), and ability to elevate relevant issues to project lead and line-management
- Attention to detail and excellent skills in record keeping / documentation

- Extensive technical writing experience in drafting stability protocols / reports, as well as method development report, method validation protocols and reports, and method SOPs
- 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

Vaxcyte, Inc.
353 Hatch Drive
Foster City, CA 94404