Job Description

Director/Associate Director, Analytical Development for Characterization

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 and QC department. The primary function of this Director level position in to lead the analytical characterization for all products in preclinical and clinical phases. This position reports directly to the Senior Director of Analytical Development and QC (AD&QC). The successful candidate will also manage and provide scientific mentorship and technical guidance for scientists in analytical development.

Essential Functions:

- Provide strategic, tactical and technical leadership in the development of analytical methods for the purpose of characterizing drug product, drug substance, intermediates and critical raw material.
- Take on end-to-end responsibility of method development for characterization 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
- Ensure characterization methods developed internally or through CROs are technically solid, robust and provide in-depth understanding of process and product that supports regulatory filing.

- Provide investigation tools and conduct studies for troubleshooting of QC testing or method related issue
- Collaborate with Formulations and Process Development to provide analytical solutions for process understanding, troubleshooting and characterization
- Author multiple regulatory submission and address health authority questions for IND and BLA approval
- Evaluate and establish contracts with CDMO/CROs for characterization method development, testing or stability studies

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.
- Must possess a solid understanding of protein chemistry and biochemistry, particularly as related to biological drug development; experience with other large molecule modalities such as ADC or vaccines is a plus.
- Extensive expertise in mass spectrometry, U/HPLC, and other analytical technologies as applied to the analysis of protein and conjugate drug products
- 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.
- Technical writing skills and experience authoring development reports, SOPs, regulatory filings, or other documents
- Ability to work in a high paced team environment, meet deadlines, and prioritize work from multiple projects.
- Strong written and verbal communication skills, and familiarity with representation on inter-disciplinary and cross-functional teams.
- Experience developing protein and conjugate assay methodologies such as proteomics, peptide mapping by MS, H/UPLC, capillary electrophoresis, SEC, CEX, icIEF and/or oligosaccharide analyses is a plus
- Understanding of FDA, EMA and other regulatory agency guidance associated with release and characterization assays
- 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

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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