# Job Description

Director/Assoc. Director, Bioassay Development

**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, highly skilled 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 development and optimization of bioassays for the lot release, characterization, and stability and formulation assessment of conjugate vaccine intermediates, and drug substance and drug product in preclinical and clinical development. The successful candidate will also manage and build a growing group of scientists and research associates and oversee work performed in CROs.

**Essential Functions:**

- Take on end-to-end strategic responsibility for bioassay method development of intermediates, drug substance and drug products.
- Lead a team of 4-5 scientists and research associate to develop, optimize, and qualify phase-appropriate a broad spectrum of immunoassay for release, stability, and formulation optimization
- Drive analytical innovation and stay on top of cutting edge bioassay technology, apply innovative approaches to problem solving, and introduce and establish novel technology in house if necessary.
- Collaborate with CROs to develop antibody critical reagents for the immunoassay development
- Provide technical tactics and oversight of antibody purification to optimize the immunoassay performance
- Develop and implement critical reagent qualification plans

- 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
- Collaborate with Formulation and Conjugation team to design and develop phase appropriate bioassay for in-process control and GMP quality control purpose.
- Author SOPs, technical reports and multiple regulatory submission when needed, and address health authority questions during various clinical phase filings
- Serves as a scientific liaison for outsourced assay development, technology transfer and data management in a CRO or CMO/CDMO environment
- 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 Biochemistry, Analytical Chemistry or Cell Biology, with 10+ years relevant industry experience; MS or BS with 15+ years of industry experience in Pharma/Diagnostic industry required
- Must be a team player, strong critical thinker, exhibit a willingness to meet project timelines and multitask effectively in a dynamic fast-paced environment under challenging timelines
- Proven track record of heading bioassay development for biologics, leading teams while managing multiple projects, experience building team and lab is highly desirable
- A strong scientific leader who can independently design, execute, and guide effective experiments with clear goals of developing robust germane bioassay methods. and effectively and skilfully troubleshoot bioassay issue during method development, transfer, validation and QC testing in a fast pace environment
- A proven track record of solving complex immunoassay and bioanalytical problems
- Experiences in hybridoma technology including optimizing the immunization and fusion process, assay development, lead antibody selection and characterization.
- Efficient in Interpreting data and communicating project status or risk mitigation strategies that drive critical decisions in CMC cross functional team
- Demonstrated leadership and track record of successfully developing different format of bioassays by utilizing appropriate methodologies
- Thorough understanding and hands on experience of MSD platform is highly desirable
- Fundamental understanding of key immunology concepts related to assessment of vaccine-induced responses required
- Solid understanding of relevant FDA, EU, and ICH regulatory guidelines and pharmacopeia as applicable to immunoassay method qualification/validation for 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 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
- Fundamental understanding of statistics and data analysis software, proficient with analytical software such as Softmax Pro and familiar with statistical software such as JMP
- Strong interpersonal skills; ability to communicate effectively both verbally and in written formats
- Strong attention to detail supported by excellent time management and organizational skills

**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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