



## **Job Description**

Senior Engineer/Associate Director, Bioconjugates  
**Vaxcyte, Inc.**

December 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:**

We are looking for a Senior Engineer with late-stage clinical or commercial experience in manufacturing, process characterization, and process validation of biologics. The successful candidate must have the ability to work in a highly collaborative manner with both internal teams and our CMO. We are looking for an outstanding team player with excellent communication skills. The Senior Engineer will work collaboratively with the process development team responsible for early-stage bioconjugation development and Phase 1 process optimization. The Senior Engineer will be directly responsible for defining an inventive process characterization strategy for a multivalent vaccine program, and will play a critical role in overseeing process validation and implementation of a process control strategy at the commercial facility to support BLA filing and commercial launch. The candidate should have demonstrated experience with risk assessments, FMEA and identifying critical and non-critical performance parameters. Depending on experience, involvement in the design or selection of a commercial launch facility with the CMC and PD leadership is likely.

This is a great opportunity to make an impact and interact cross-functionally to take Vaxcyte's lead program to the next level toward the company's first licensure application.

## **Essential Functions:**

- Perform and facilitate completion of process design and characterization deliverables required for commercial manufacture of multiple drug substances.
- Contribute to assessing internal or external options to complete Process Characterization and validation in a timely manner with an economy of resources and materials.
- Support late stage process validation activities (including PPQ) at CMO(s) or Vaxcyte owned facility.

- Facilitate and lead process risk assessments to drive process control strategies and help prioritize characterization experiments.
- Independently or cooperatively design and execute studies supporting process characterization and validation.
- Write and contribute to process characterization, scale-up, process control and process validation documents including strategy documents, test plans and protocols, control and process descriptions, plan summaries, SOPs. Contribute to authoring related sections to support regulatory filings.
- Work with internal Process Development, Analytical Development and CMC and QA leadership and CMO's process development and GMP manufacturing team members to ensure a robust, scalable production process.

**Requirements:**

- PhD or MS degree in biochemical, chemical, or biomedical engineering with 6-8 years of relevant experience. Bachelor's degree with appreciable experience (8-12 years) will be considered as well.
- Working knowledge of US FDA CFRs and European EMA, including ICH regulations
- In-depth knowledge of equipment, operations, and engineering principles involved in biologics GMP manufacturing
- Must have strong engineering, statistical, or scientific knowledge appropriate for job requirements. Experience with risk assessment exercises, FMEA or RAMM is required.
- Experience in protein downstream purification.
- Experience with Tangential Flow Filtration development is highly desirable.
- Experience with manufacturing of bioconjugates (ADCs, protein conjugates, glycoconjugates, nanoparticles) is highly desirable.
- Ability to understand and keep track of regulatory expectations and industry best practices.
- Process control strategy, tech transfer and process validation experience.
- Ability to think outside the box and combine thoroughness and inventive approaches to complex process characterization using DoE and aspects of QbD.
- Experience with biologics commercial launch highly desirable.
- Excellent verbal and written communication skills.
- Must have excellent organization skills and the ability to handle multiple tasks.
- Highly motivated, and willingness to acquire new skills and ability to work independently as well as collaboratively in a matrix environment.
- Ability to travel internationally is required (not more than an average of once per quarter)

**Reports to:** Director, Bioconjugates Development and Manufacturing

**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