Job Description

Senior Engineer, Conjugation Development

Vaxcyte Inc

March 2021

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:

The Development organization is comprised of four Process teams: Protein, Polysaccharide, Conjugate Drug Substance (Conjugation), and Drug Product. These Process Development teams are supported by Analytical Development and Formulation Development teams. Vaxcyte is looking for a Senior Engineer to join the Conjugation Development team and take the lead in developing scaled-up processes to supply Phase 3 and Commercial quantities of the VAX-24 Conjugate Drug Substances.

Essential Functions:

- Take the lead in scale-up activities to support manufacture of Phase 3 and Commercial scale quantities of the VAX-24 Conjugate Drug Substances; work with fellow group members to develop appropriate scale-down models
- In concert with CMO, identify and implement the appropriate equipment required to perform late-stage manufacturing
- Contribute to CMO Manufacturing oversight via document review, person in plant responsibilities, and troubleshooting when necessary
- Facilitate cross-functional process risk analysis using appropriate tools such as FMEA, leading to the identification of CPPs and CQAs
- Help to define the scope and strategy of late stage process development activities such as process characterization
- Present/communicate data to the Conjugation Development team as well as broader CMC team
- Serve as a guide and mentor to junior team members

Requirements:

- PhD in Chemical or Biochemical Engineering, with 2+ years of industry experience; MS with 5+ years of industry experience; or BS with 10+ years of industry experience
- In depth bioconjugate or protein purification knowledge and experience, including expertise in tangential flow filtration (TFF) and size exclusion chromatography (SEC) process scaling and optimization; experience with reactor scale up is a plus
- Both practical experience with and theoretical knowledge of engineering principles involved in scaling processes from development lab to pilot / manufacturing plant
- Working knowledge of the requirements of GMP manufacturing, preferably with hands-on GMP experience through either a Manufacturing or MSAT role
- Experience working with CMOs highly desired; ability to effectively transfer processes to CMO, and to oversee development and manufacturing activities performed at CMO; ability to travel to CMO (some international travel required) to perform person-in-plant oversight activities
- Solid understanding of the principals of DoE (Design of Experiments); practical experience with DoE software; proficient in the design and interpretation of statistically modelled experiments
- Experience with late-stage process development activities such as risk assessments (eg, FMEA) and identification of CPPs and CQAs is a plus
- Experience writing IND sections is a plus
- Demonstrated success working in a cross-functional team environment on multiple projects; ability to work both on a team (as member and/or leader) and independently to deliver results
- Strong interpersonal skills, with excellent written and verbal communication skills

Reports to: Associate Director, Conjugation Development

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