Job Description

Senior/Principle Scientist of Drug Product Engineering

April 2021

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

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 strain coverage, 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 the Formulation and Drug Product Development team. The primary responsibility for the incumbent will be to support the late stage activities of the Drug Product (DP) team in readiness for phase 3 clinical studies and through commercial launch.

Due to the number of antigens and the suspended adjuvant system, this is arguably one of the most complex Drug Products in clinical development, so it is an incredible opportunity for the right candidate to make a significant impact on the product, the company, and the industry. This is a senior position and will require the candidate to have a high level of independence, scientific judgement, and leadership abilities.

Essential Activities:

- Aid in evaluation, selection, and oversight of an appropriate fill finish CMO service provider to support early, late, and commercial stage manufacturing deliverables
- In concert with the CMC team and external guidance, design and oversee late-stage process characterization and process validation strategies consistent with CMC-regulatory guidance
- Provide engineering guidance, in conjunction with to generate the appropriate solutions for successful commercial mixing of the DP intermediates that allows compounding of 24 Drug Substances (DS)
- Scaleup of mixing solutions for the DP bulk suspension mixture to ensure adequate homogeneity during the DP final fill and facilitation of internal development work.

- Generation, testing, and validation of the above mixing solutions for the DP bulk suspension mixture to ensure adequate homogeneity during the DP final fill.
- Participate cross-functional process risk analysis using appropriate tools such as FMEA, leading to the identification of CPPs and CQAs, in conjunction with other Regulatory/CMC leaders
- Ultimately establish supply chain logistics for the shipping of DS/intermediates/DP bulk under liquid or frozen conditions with suitable container closure systems
- Experience of the specifics in transferring from a vial to pre-filled syringe solution from an engineering perspective

Requirements:

- BSc or MSc in Chemical Engineering, Process Engineering, Pharmaceutical Development preferred, with >10 year of industrial experience; or PhD with >7 years.
- Experience in late-stage clinical manufacturing within fill finish sites under GMP regulations; it is mandatory that the successful candidate be entirely conversant with GMP manufacturing
- Experience of chemical engineering in the biological manufacturing space, leading to custom engineering solutions
- Experience in the progression of such engineering solutions from early to late clinical stage and through commercial launch, preferably in the fill/finish arena
- Experience in the development of scaleup/down models and how they pertain to mixing of DP bulk, preferably suspension systems
- Experience in validation of DP processes, including the use of QbD as required
- Experience in leading the evaluation, selection and oversight of CMOs that perform DP fill finish activities
- An understanding of the design and management of logistical supply chains to enable bespoke fill finish activities
- Strong interpersonal and leadership skills; ability to communicate effectively both verbally and in written formats
- Ability to work within in a fast-paced, cross functional environment, multitasking as needed

Reports to: Director of Formulation and Drug Product 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

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