Job Description

Director/Associate Director, Method Development and Characterization

Vaxcyte, Inc.

July 2020

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 development and 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 for Analytical Development and characterization, drive analytical innovation, provide scientific oversight of analytical method development, qualification and data generated by internal and contract labs
- Take on end-to-end responsibility of method development for characterization and quality control of proteins, bacterial polysaccharides, polysaccharide-protein conjugates, and adjuvanted vaccines product. Responsibility also includes resource planning, team productivity and timeline management of the deliverables.
- Manage scientists of various levels, provide technical direction, mentorship and coaching
- Cultivate a cohesive, innovative, nimble and productive team environment
- Ensure methods developed internally or through CROs are technically solid and robust
- Partner with Assoc Director of Method Transfer and QC to ensure successful method transfer, implementation and validation at the CMO. Provide necessary trouble shooting to CMO
- Collaborate with Formulations and Process Development to provide analytical solutions for process understanding, troubleshooting and characterization
- Design and oversee stability studies of critical material, intermediates, drug substance and drug product of company's conjugate vaccine projects. This will include R&D stability studies to support process development, toxicology nonclinical studies, or GMP clinical studies
- Responsible for setting product expiry based on the stability data analysis and trending.
- Author multiple regulatory submission and address health authority questions for IND and BLA approval
- Evaluate and establish contracts with CDMO/CROs for method development, testing or stability studies
- Provide appropriate CRO/CDMO oversight by reviewing analytical method development data, reviewing and approving analytical method validation protocols, reports, and analytical method SOPs

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
- Background in developing methods for transfer to Quality Control
- 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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