Job Description

Vice President, Regulatory Affairs

SutroVax Inc.

April 3, 2017

Company Profile:

SutroVax is a biopharmaceutical company dedicated to the delivery of best-in-class conjugate vaccines and novel complex antigen-based vaccines to prevent serious infectious diseases. SutroVax's lead product candidate is a pneumococcal conjugate vaccine (PCV) that is designed to prevent invasive pneumococcal disease caused by *Streptococcus pneumoniae.* SutroVax's broad-spectrum PCV is designed to provide expanded protection against circulating strains of *pneumococcus* and has the potential to replace the current vaccines used in infants and adults. SutroVax has generated pre-clinical proof-of-concept with its broad-spectrum PCV when compared head-to-head to current vaccines using well accepted immunological endpoints. In addition to its lead PCV product candidate, the Company also has a promising antigen discovery effort and early-stage pipeline addressing other disease areas.

SutroVax's conjugate vaccines are developed utilizing the Company's exclusive rights to Sutro Biopharma's Xpress CF Platform, a cell-free protein synthesis technology. SutroVax closed its Series B round in 2017 and is financed by an international syndicate of experienced, blue-chip venture capital and corporate venture investors with $88M in capital raised since inception.

Summary:

SutroVax is looking for an energetic and brilliant Vice President, Regulatory Affairs who will be responsible for regulatory strategy, oversight, and direction of the Company's vaccine development programs. The successful candidate will bring a history of effectively leading cross functional vaccine development teams and interacting with the FDA, the EMA and other international regulatory bodies. This position requires a hands-on operating style, with attention to detail, budgets and timelines.

Essential Functions:

- Develop vaccine product profile and approval strategy in US and EU for potential best-in-class pneumococcal conjugate vaccine
- Provide leadership in program management, including development of overarching project timeline and execution plan
- Direct and manage company interactions with FDA and other health authorities
- Direct and manage the preparation, submission, and maintenance of INDs, NDAs, and other regulatory applications
- Assist in designing and executing Clinical Studies required for Regulatory Approvals, including data analysis
- Inform leadership team of regulatory status of products and significant regulatory issues
- Provide counsel, training, and interpretation of FDA and other regulatory issues to Company personnel and assist as a liaison between the Company and regulatory authorities
- Obtain and disseminate information regarding current activities, trends, and changes in the regulatory environment

- Host FDA/third party regulatory audits and ensure subsequent conformance on findings & observations

Skills, knowledge, and experience:

- Bachelor's degree required; Master's degree or Ph.D. preferred
- 15 years of experience in the vaccine industry including 10 years of relevant experience within Regulatory Affairs
- Proficient in the delivery and conduct of all Regulatory Affairs activities including, but not limited to: submissions, publishing, review, and oversight
- Thorough understanding of regulations of ICH, FDA, and EMA.
- Knowledge of GLP, GMP, and GCP regulations
- A proven track record of successful vaccine development coupled with positive working relationships with regulatory agencies is required
- Ability to work well under pressure and adhere to deadlines
- Proven ability to manage and grow a team
- Strong interpersonal skills, with excellent written and verbal communication skills
- Willing to travel both domestic and international

Reports to: Chief Executive Officer or Chief Medical Officer

Location: Foster City, California

Compensation:
The compensation package will be competitive and includes comprehensive benefits and an equity component.

Send resumes to:
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