ICOSAVAX

Icosavax Job Description

Director or Senior Director, Regulatory

SUMMARY: Icosavax, Inc. is a start-up biotechnology company focused on developing potential "best-in-class" vaccines for respiratory diseases in older adults using a protein-based virus-like particle (VLP) vaccine platform. This VLP technology allows for stable, multivalent display of immunogens, driving a more robust immune response, and therefore should yield improved efficacy compared with conventional approaches. Icosavax has an experienced management team and has raised $150M to date. Icosavax has two vaccine candidates expected to move into clinical studies in 2021: a respiratory syncytial virus (RSV) vaccine and a SARS-CoV-2 vaccine. In addition, Icosavax is rapidly developing a broad pipeline of other vaccine candidates using the VLP platform technology.

The Icosavax Clinical and Regulatory group is seeking a Director/Sr Director level regulatory professional with a strong background in vaccine development to lead the regulatory strategy of Icosavax's early-stage vaccine programs. This individual will serve as a Regulatory Lead for Icosavax's development programs and as a subject matter expert, who works collaboratively with internal and external partners. The successful candidate will understand what it takes to excel in a dynamic small company environment. They will be part of a cross-functional team that helps to drive and push one another to continued levels of success.

OBJECTIVES:

- Oversee the successful regulatory strategy for development and registration of multiple vaccine candidates.
- Support integrated product development plans with vaccine regulatory plans, leading to the successful completion of regulatory filings, including INDs, CTAs, IMPDs, and future marketing applications.
- Execute the regulatory strategy including coordination of regulatory communications with competent authorities in multiple jurisdictions, successful regulatory submissions, and pursuit of appropriate regulatory designations for vaccine candidates.

ACCOUNTABILITIES:

- Serve as Regulatory Lead and provide Regulatory leadership within Regulatory function and on cross-functional Project teams. Lead coordination, preparation with internal and external partners, and successful resolution of regulatory interactions (e.g., scheduled meetings, regulatory correspondence, inspections)
- Demonstrate In depth knowledge and application of global regulatory guidelines regarding investigational new drug (IND), clinical trial applications (CTAs), biologics license applications (BLAs), or post approval changes.
- Accountable for the delivery of all regulatory milestones for high-complexity products including assessment of the probability of regulatory success and risk mitigation measures.
- Lead development and execution of detailed, global regulatory submissions of INDs, CTAs, BLAs, or post approval change documentation according to defined timelines.

- Collaborate with partner groups in critical review of submissions to ensure compliance, scientific excellence, accuracy and completeness of submissions.
- Provide regulatory leadership as needed in product in-license/due diligence review, product divestment and product withdrawal.
- Review detailed scientific information and assess whether technical arguments are presented clearly and conclusions are adequately supported by data.
- Demonstrate superior oral and written communication skills in multicultural settings and communicate complex issues in a succinct and logical manner. Strong listening skills.
- Connect and understand requirements of related fields (e.g., manufacturing, analytical, quality assurance, nonclinical, and clinical development)
- Generate innovative solutions to complex regulatory problems and effectively work with and communicate to key stakeholders.
- Able to roll up sleeves/respond to dynamic change. Be flexible in responding to changing priorities or dealing with unexpected events.
- Demonstrate effective leadership, communication, interpersonal and negotiating skills with cross functional partners and health authorities.
- Contribute to a high-integrity, high-performance and enjoyable team culture experience desirable. Sense of humor preferred.

EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

Education:

- BS or MS in a biological science, engineering, or a related field. (Fields of study include Biology, Microbiology, Virology, Molecular Biology, Chemical Engineering, Chemistry or Biochemistry)

Experience, Knowledge and Skills:

- At least 10 years of relevant Regulatory experience; with a focus on vaccine development.
- Regulatory Affairs Certification (RAC) or other regulatory certification preferred.

PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment.
- Some travel may be required.

LOCATION:

- Location is Seattle Washington, USA.

Please send cover letter and resume to careers@icosavax.com