ICOSAVAX

Icosavax Job Description

Senior Director, Regulatory

SUMMARY: Icosavax, Inc. (NASDAQ: ICVX) is a publicly traded biopharmaceutical company leveraging its innovative VLP platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases. Icosavax's VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which it believes will induce broad, robust, and durable protection against the specific viruses targeted. Icosavax's pipeline includes vaccine candidates targeting respiratory syncytial virus (RSV), human metapneumovirus (hMPV), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Based in Seattle, Icosavax was formed in 2017 to advance the breakthrough VLP technology from the Institute for Protein Design at the University of Washington with the goal to discover, develop, and commercialize vaccines against infectious diseases.

The Icosavax Clinical and Regulatory group is seeking a 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.

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