ICOSAVAX

Job Announcement

Director, Quality Control

SUMMARY:

Icosavax, Inc. is a publicly traded (NASDAQ: ICVX) 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). 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. Icosavax has an experienced management team, has raised over $350M to date, and is in Seattle, Washington.

OBJECTIVE:

Icosavax seeks to hire a Director, Quality Control with biotech vaccine experience for our Quality Team. This position will play a key role in managing the lifecycle of GMP testing methods in both early and late stage vaccine development. The successful candidate will interface with key Icosavax functional and cross-functional teams, as well as our CDMO/CRO partners for vaccine development.

The successful candidate will be highly self-motivated, productive, a quick learner, and creative. They will be comfortable partnering with Icosavax's CMC Development to manage all aspects of GMP testing as well as supporting the Clinical Development team as an SME for bioanalytical testing. Successful candidates will have excellent problem-solving skills as well as strong written and verbal communication skills. This position requires an independent strategic thinker motivated by performance excellence and team success, someone who can roll up their sleeves and assist where needed, work within an evolving matrixed organization, support lean operations teams, and partner with employees at all levels of the organization. The successful candidate will be a positive and enthusiastic team player, a leader, able to work with moderate guidance and take pride in the quality and timely delivery of their work. The ability to mentor associates across the organization on GMPs and topics such as QC testing, stability testing, regulatory writing, current and best-industry practices, and inspection readiness will be significant preferred characteristics for the successful candidate.

RESPONSIBILITIES

- Collaborate across all disciplines within Icosavax to progress vaccine candidates including early and late-stage CMC development.

- Deliver analytical characterization packages for vaccine candidates at the drug substance and drug product stages, including adjuvant-containing drug products.
- Oversee analytical method qualification, validation and routine QC testing at third party vendors responsible for delivering GMP drug substance and drug product to Icosavax for use in human clinical trials to be conducted on a global basis.
- Oversee the stability program for all Icosavax products.
- Oversee the qualification and management of reference materials and critical test reagents.
- Transition analytical methods for vaccine candidates from early to late-stage CMC development in support of pivotal trial CTM supply.
- Support overall CMC platform development and delivery of GMP material by participating on cross-functional teams responsible for delivering clinical trial material in a time and cost-effective manner aligned with Icosavax strategy.
- Make critical decisions and trade-offs that improve resource utilization and ensure program success while maintaining an appropriate risk profile.
- Write and review CMC sections for CTD documents.
- Act as SME in support of bioanalytical test method development.
- Support QA audits for the vendor qualification program.
- Act as delegate for the VP of Quality.

QUALIFICATIONS:

- M.S. in chemistry, biochemistry, or closely related field, or equivalent experience applicable to the job responsibilities
- 10+ years of applicable QC and cross-functional leadership experience including in a startup environment
- Biologics and analytical development experience required; strong preference for recombinant protein vaccine experience, especially VLP-based antigens and adjuvant-based formulation systems.
- Deep experience with structural characterization of complex proteins in support of regulatory filings and aligned with the principles of well characterized biological products.
- Proven ability to function in multidisciplinary cross functional team environments.
- Fifteen or more years of relevant industry experience including transition of early-stage QC methods to late-stage programs including preparation of regulatory filings.
- Familiarity with US and EU GMP regulations, and ICH Guidelines
- Excellent self-management, organizational, and verbal/written communication skills.
- Experience working as part of multi-functional team.
- Effectively represent the Quality organization both internally and externally.
- Experience with electronic quality management systems preferred.
- Proficiency with standard project management, virtual communication, and cloud-based documentation tools.

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