ICOSAVAX

Icosavax Job Description

Manager, Quality Assurance

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 $65M to date. Icosavax has two vaccine candidates expected to move into clinical studies in 2021 including 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.

Icosavax seeks to hire a Manager, Quality Assurance. This position will play a key role in developing and maintaining the Quality Management System. Based in Seattle, WA, this role will report into the Sr. Director of Quality, within the Technical Operations group and will support cross-functional quality management.

OBJECTIVES:

- Effectively manage the Quality Management System that support GxP (GLP, GMP, GCP) activities for preclinical to Phase 3 activities at Icosavax.
- Manage Quality Assurance activities including oversight of contract GxP vendors.
- Independently provide quality assurance guidance and support to R&D, CMC and Clinical groups within Icosavax.
- Lead efforts in continuous improvement of GxP compliance for Icosavax.

ACCOUNTABILITIES:

- Lead audits at contract manufacturing, testing, packaging, and warehouse/distribution operations to assure adherence to regulatory requirements. Approve audit reports., develop annual audit schedules and approve audit reports, and follow up on corrective actions.
- Ensure operations at contract facilities (CDMOs, CROs) are conducted in accordance with quality agreements.
- Lead investigations into Good Manufacturing Practice (GMP) related issues or problems associated with audits, batch records, and complaints. Manage manufacturing and testing deviations and out-of-specification investigations.
- Oversee internal CAPA management.
- Review and approve batch and test records, prepare annual product reviews, process technical complaints.
- Review and approve documentation for tech transfer and validation of analytical methods and manufacturing processes.

- Approve stability protocols and final reports. Ensure expiration dates are assigned per site procedures.
- Conduct internal audits.
- Maintain QA records according to applicable regulatory requirements and Icosavax policy. Draft and review internal GxP documents such as standard operating procedures, certificates of analysis, and specifications. Review and approve release and stability test results and manage associated documentation.
- Provide quality metrics to Icosavax management.
- Manage Icosavax's training program in appropriate areas of regulatory compliance.
- Other duties as assigned.

EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

Education:

- Minimum of bachelor's degree in Chemistry, Biology, Engineering or related scientific field.

Experience, Knowledge and Skills:

- Minimum of 5 years experience in quality or regulatory compliance within the pharmaceutical, biologics, or other related industries.
- GMP QA experience required. GLP and GCP QA experience a preferred.
- Excellent communication skills both oral and written.
- Experience overseeing contract manufacturing and testing vendors.
- Effectively represent Quality Assurance, both internally and externally.
- Experience with US and EU regulatory requirements for pharmaceuticals.
- Experience with electronic Quality Management Systems (eQMS) preferred.

PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment (i.e. computers, phones, etc.).

TRAVEL REQUIREMENTS:

- Location is Seattle Washington, USA.
- Willingness to travel to various meetings or client sites, including overnight trips. Some international travel may be required.
- Requires approximately 25% travel.

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