ICOSAVAX

Icosavax Job Description

Senior Quality Assurance Specialist

SUMMARY: Icosavax, Inc. is a 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 are expected to induce improved immunogenicity compared with conventional vaccine approaches. Icosavax has an experienced management team and has recently completed its Initial Public Offering. Icosavax has a SARS-CoV-2 vaccine in clinical trials and a respiratory syncytial virus (RSV) vaccine expected to start clinical trials in Q3 2021. In addition, Icosavax is rapidly developing a broad pipeline of other vaccine candidates using their VLP platform technology. Our programs currently range from early discovery through IND enabling nonclinical/CMC activities, to regulatory submissions and Phase 1 clinical studies. Icosavax conducts its development work in a semi-virtual model, leveraging both internal laboratory facilities as well as partnering with many CROs, CDMOs, consultants and KOLs.

OBJECTIVE:
Icosavax seeks to hire a Senior Quality Assurance Specialist with biotech vaccine experience for our Quality Team. This position will play a key role in supporting GMP/GCP quality operations including, CMC Development, Manufacturing, Clinical and Quality Systems. The successful candidate will interface with key Icosavax functional and cross-functional teams, as well as our CDMO/CRO partners for vaccine development, manufacturing, testing, supply chain and clinical activities.

The successful candidate will be highly self-motivated, productive, a quick learner, and creative. They will be comfortable partnering with Icosavax's CMC Development and Clinical Teams to manage GMP/GCP activities and issue escalation. They 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, working within a lean operations team and partnering with employees at all levels of the organization. The successful candidate will be a positive and enthusiastic team player, able to work with moderate guidance and take pride in the quality and timely delivery of their work.

RESPONSIBILITIES

- Conduct audits at contract manufacturing, research, testing, packaging, and warehouse/distribution operations. Support development of annual audit schedules.
- Review and approve documentation of GMP/GCP activities at contract facilities.
- Responsibilities for day-to-day interactions with contract facilities.

- Conduct investigation into GMP and GCP related issues or problems associated with audit, batch records, complaints, and clinical studies. Approve deviations and investigations into out-of-specification results.
- Approve internal CAPA. Manage internal CAPA system.
- Review and approve manufacturing batch records and Quality Control test records.
- Review and approve documentation for tech transfer and qualification/validation of analytical method 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 GMP/GCP documents such as standard operating procedures, certificates of analysis and specifications.
- Provide QA tracking and trending information to Icosavax management.
- Provide GMP/GCP training to Icosavax staff and contractors.
- Other duties as assigned.

Qualifications:

- Bachelor's Degree or higher in scientific discipline.
- Minimum of 6 years of experience in quality or regulatory compliance within the pharmaceutical, biologics or other related industries.
- GMP and/or GCP experience required.
- Excellent communication skills both oral and written.
- Experience working as part of multi-functional team.
- Effetely 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.

PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment (i.e., computers, phones, etc.).
- May require 25% offsite travel. Some international travel may be required.

Location for this role is at the Icosavax headquarters in Seattle, Washington, USA.

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