ICOSAVAX

Job Announcement

Associate Director, QA (GCP)

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.

OBJECTIVE:

Icosavax seeks to hire an Associate Director, QA (GCP) with biotech vaccine experience for our Quality Team. This position will play a key role in supporting Clinical Development and development of our 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 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 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, 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, 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 GCP and topics such as audits, current and best-industry practices and inspection readiness will be a significant preferred characteristic for the successful candidate.

RESPONSIBILITIES:

- Represent Quality Assurance on key sponsor and study project teams including dissemination of key Quality information, guidance, training, and support.
- Ensure clinical processes are conducted in accordance with company procedures and applicable regulatory GCP requirements, sponsor SOPs, study protocols and current industry standards, regulations, and guidelines.
- Perform GCP/GLP/PV Vendor Qualification process as per procedure.

- Lead GCP/GLP/PV External and Internal Audit schedule.
- Track audit report completion, audit responses from vendors, and any remaining open observations via a CAPA to closure.
- Interact with contract auditors in the scheduling process, kick-off meetings with auditors and internal groups as well as assists in the drafting of audit plans, confirmation letters and agendas, etc.
- Collaborate with cross-functional departments to ensure timely implementation of document change requests.
- Participate in regulatory inspections, both site (as requested) and sponsor.
- Writing, reviewing, and revising SOPs to assess clarity, consistency, and compliance with regulatory requirements/internal standards. Help align sponsor SOPs with best CQA practices and GXP compliance.
- Manage product technical complaints per company procedures.
- Manage internal/vendor GCP/GLP quality events (deviations) and participate in investigations per company procedures. Monitor internal/vendor CAPAs for content, progress, and resolution.
- Escalate issues of critical non-compliance and/or lack of urgency in remediation to Quality Assurance and Clinical Operations teams.

EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

- Bachelor's Degree or higher in a scientific discipline.
- Minimum of 8 years of experience in quality or regulatory compliance within the pharmaceutical, biologics or other related industries, including international GCP experience preferred. Experience with inspections and audits, in support of regulatory filing, is preferred.
- GCP/GLP experience required, PV experience preferred.
- Excellent communication skills both oral and written.
- 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.

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

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