



Job Announcement

Director, Drug Substance Operations

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. Icosavax is based in Seattle, WA.

Icosavax seeks a Director, Drug Substance Operations to support CMC efforts by leading CMO relationship management for the company. The position is responsible for providing oversight, management, and performance of CMO relationships and delivering drug substance in support of clinical trials and process validation campaigns.

The successful candidate will be a self-motivated professional with a high degree of emotional intelligence. They will have a significant background in technical transfer and manufacturing operations. Excellent problem-solving skills as well as strong written and verbal communication skills are required. This position requires someone who can roll up their sleeves and assist where needed and who can partner with employees at all levels of the organization. They will enjoy working on a team but be able to work with moderate guidance and take pride in the quality and timely delivery of their work.

RESPONSIBILITIES:

- Lead internal Icosavax Drug Substance Operations team and serve as primary point-of-contact between Icosavax and drug substance CMO organizations (multiple vendors). Responsible for oversight, management, and performance of CMO relationships.
- Lead Icosavax team responsible for phase-appropriate manufacturing and release of clinical trial drug substance supplies. Includes E. coli and CHO expressed proteins manufactured using platform processes.
- Ensure that late-stage CMC deliverables such as process characterization and process validation reports in support of DS manufacturing are of the appropriate quality and are delivered in a timely fashion.
- Own cross-functional drug substance raw materials risk assessment processes and oversee implementation of action items generated by the assessments.



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- Ensure drug substance manufacturing materials and supplies are ordered and released in timely support of the manufacturing plan. This may include detailed oversight of CMO procurement and inventory management as well as establishment and warehousing of Icosavax-owned inventory.
 - Support the development and maintenance of cost-of-goods models for commercial drug substance supply.
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EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

- Bachelor's degree in science or engineering field
- 15 years industry experience including significant hands-on recombinant protein manufacturing/manufacturing sciences experience in a fast-paced environment
- In-depth technical knowledge of large-scale low-bioburden recombinant protein manufacturing
- Proven technical project management skills, PMP preferred
- Proven ability to function in multidisciplinary cross functional team environments.
- Expert knowledge of GMP, CFR, and ICH Guidelines
- Excellent self-management, organizational, and verbal/written communication skills.

Travel demands: 20% expected.

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