

## Director, Drug Product Operations

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### **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 Director/Senior Director, Drug Product Operation with vaccine supply chain and external manufacturing experience. This position will play a key role in developing our supply chain strategy and establishing our manufacturing network for clinical trial and commercial drug product supply. The successful candidate will lead ongoing clinical trial drug product supply manufacturing (external), further develop the incoming raw materials supply chain, establish a networked strategy for commercial supply of high-volume vaccines presented as pre-filled syringes and multi-dose vials, lead drug product process performance qualifications and support regulatory filings.

Additionally, the successful candidate will be highly self-motivated, productive, a quick learner, and creative. They will be comfortable working on cross-functional teams in a fast-paced environment. They will have excellent organizational 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 has deep industry experience and is willing to roll up their sleeves to deliver projects in partnership with employees at all levels of the organization. The successful candidate will be an enthusiastic team player with a can-do attitude that takes pride in the quality and timely delivery of their work.

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### **RESPONSIBILITIES:**

- Lead development of corporate supply chain strategy including assessment of contract third-party supply, supply from sponsor-owned assets installed/operated at



## Icosavax Job Description

CMO/partner facilities, potential internal capacity build and the appropriate mix thereof in the context of a range of demand forecasts.

- Build fill finish and packaging supply chains for global commercial supply of multiple, high-volume prophylactic vaccines; presentations include MDV and PFS packaged for distribution and delivered to depots.
- Ensure manufacturing materials and supplies are ordered and released in timely support of the manufacturing plan including detailed oversight of CMO procurement and inventory management and establishment and warehousing of Icosavax-owned inventory.
- Qualify and manage multiple drug product CMOs. Serve as primary point of contact for CMO project execution.
- Lead Icosavax team responsible for phase-appropriate manufacturing, testing and release of clinical trial drug product supplies. Includes formulation and fill finish as well as packaging, labeling and delivery to depots/clinical sites.
- Own cross-functional raw materials risk assessment processes and oversee implementation of action items generated by the assessments.
- Develop cost-of-goods models for commercial drug product supply

### QUALIFICATIONS:

- Bachelor's Degree in science or engineering field
- Minimum of 15 years of experience in pharmaceutical, biologics or other related industries including significant commercial fill finish experience
- In-depth technical knowledge of large-scale aseptic filling of Biologics including operation of high volume pre-filled syringe isolator lines.
- Proven technical project management skills
- Experience working as part of a multi-disciplinary, cross-functional team.
- Expert knowledge of GMP, CFR, and ICH guidelines.
- Excellent self-management, organizational and verbal/written communication skills.
- Demonstrated proficiency in data analysis and verbal and written technical communication.

### PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment (i.e., computers, phones, etc.).
- May require 20% offsite travel including potential overnight travel to various meetings or client sites. Some international travel may be required.

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The preferred location for this role is at Icosavax headquarters in Seattle, Washington, USA.

**Please send cover letter and resume to [careers@icosavax.com](mailto:careers@icosavax.com)**