



## Director, Analytical and Formulation Development

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**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.

The Director, Analytical and Formulation Development will collaborate across all disciplines within Icosavax to progress vaccine candidates including early and late-stage CMC development.

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### JOB DUTIES:

- Develop techniques and methods for the evaluation of the potency and stability of vaccine candidates as part of the Discovery to CMC translational down selection process.
- Deliver analytical characterization packages for vaccine candidates at the drug substance and drug product stages, including adjuvant-containing drug products.
- Deliver development stage-appropriate drug substance and drug product (including adjuvant-containing) formulations to support vaccine candidates as they progress through CMC development.
- Collaborate with third party vendors to supply materials for use in animal toxicology studies and early-phase and late-phase human clinical trials.
- Transition vaccine candidates from early to late-stage CMC development in support of pivotal trial CTM supply.
- Support the selection of antigen candidates including down selection from a pool of candidates generated by the Discovery function to a single candidate that will be progressed into clinical development
- Provide analytical development and formulation technical expertise and oversight to internal and external collaborators (e.g. CDMO) to ensure strategies and tactics are appropriate, effective, and aligned with Icosavax strategy.
- Support overall CMC platform development and delivery of GMP material by participating on cross-functional teams responsible for delivering clinical trial material in a time and cost-effective manner aligned with Icosavax strategy.



## Icosavax Job Description

- Make critical decisions and trade-offs that improve resource utilization and ensure program success while maintaining an appropriate risk profile.
- Deliver CMC sections for CTD documents.

### **EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:**

#### **Education:**

- PhD in chemistry, biochemistry, or closely related field, or equivalent experience applicable to the job responsibilities

#### **Experience, Knowledge and Skills:**

- 10+ years Biologics and analytical development experience required; strong preference for recombinant protein vaccine experience, especially VLP-based antigens and adjuvant-based formulation systems.
- Deep experience with structural characterization of complex proteins in support of regulatory filings and aligned with the principles of well characterized biological products.
- Proven ability to function in multidisciplinary cross functional team environments.
- Fifteen or more years of relevant industry experience including transition of early-stage QC methods to late-stage programs including preparation of regulatory filings.
- Familiarity with GMP, CFR, and ICH Guidelines
- Excellent self-management, organizational, and verbal/written communication skills.
- Experience with Influenza vaccine development and interactions with the Essential Regulatory Laboratories, desired

### **PHYSICAL DEMANDS:**

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

- Location: Remote/USA
- Must be eligible to work in the USA
- To reduce the presence and severity of COVID-19 cases in the workplace and in our communities, Icosavax requires all newly hired employees to be fully vaccinated against COVID-19 before commencing employment, subject to reasonable accommodation and other requirements of applicable federal, state and local law.

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



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