Job Description

Manager / Senior Manager, Clinical Supply Chain

Why Nuvig

Be a part of a potential game-changer for patients with autoimmune disease! Nuvig Therapeutics is developing novel immune therapies to treat a broad spectrum of autoimmune diseases. Our treatments are developed to be active for a broad spectrum of autoimmune diseases, without the inherent side effects and safety concerns of long-term treatment with existing therapies, such as immunodeficiency and increased cancer risk. In early 2024, our Development Candidate NVG-2089 advanced to a Ph 1b trial in patients. This is an opportunity to play a key role in the success of an early-stage organization working to advance innovative and transformational therapies to improve treatment options for patients. Join us in making a dramatic difference in patients' lives!

Position Summary

We are seeking a Manager, Clinical Supply Chain to oversee clinical supply chain activities to support ongoing and future clinical studies for biologic products in development. The ideal candidate will define objectives and priorities, establish milestones, and anticipate and mitigate risks while maintaining strong attention to detail. The candidate will also help to establish and integrate this function within Nuvig Therapeutics and work cross-functionally with CMC and Clinical Operations to drive clinical programs. We are seeking a candidate with strong external CMO/CRO management experience in support of global clinical trials. The Manager/Senior Manager, Clinical Supply Chain will report to the Director of CMC.

Responsibilities

- Oversee end-to-end clinical supply chain activities including but not limited to:
    - Set up, manage, and monitor global distribution networks to supply Investigational Product (IP) to global clinical trials. Ensure Import/Export documentation is available as required
    - Oversee IP shipment orders per supply plans or as requested by Clinical Operations
    - Design and implement strategic plans to forecast drug demand based on clinical study protocols
    - Storage and inventory management
    - Develop and manage label text, coordinate translations and proofing processes
- Provide effective vendor oversight and manage vendor relationships ensuring timelines are met.
- Review and manage RFPs, vendor contracts, and budgeting and invoicing processes.
- Develop strategy and oversee drug return and destruction activities at vendors.
- Work within a broad CMC team to develop resupply strategies based on inventory and shelf-life of clinical supplies. Assess and prepare for challenges with IP expiry dating.
- Interface with CMC, Quality Assurance, Clinical Operations, Regulatory Affairs, and others as required to meet project deliverables.
- Develop and establish Standard Operating Procedures (SOPs) as required. Review and revise departmental SOPs to streamline and improve current practices.
- Proactively identify potential supply chain issues, provide analysis, and recommend solutions.
- Supports logistics for transportation of bulk drug substance and drug product across supply chain.

Knowledge and Skill Requirements

- Bachelor's Degree, preferably in a scientific or engineering discipline
- Minimum 5 years of relevant industry experience with pharmaceutical clinical supply management. Rare Disease experience is a plus.

- Working knowledge of GMP and GCP.
- Familiarity with various clinical trial designs (randomized, double-blind, etc.).
- Experience working with external vendors and collaborators with strong interpersonal skills.
- Demonstrated experience with clinical trial process from a supply chain perspective from study start up through completion, including shipping.
- Demonstrated experience in inventory management and forecasting drug supply needs (global experience preferred).
- Ability to manage multiple projects simultaneously.
- Effective cross-functional collaborator and communicator
- Excellent verbal and written communication (technical writing, PowerPoint).
- Ability to manage complexity and ambiguity in a fast-paced work environment.

What We Offer

- A culture inspired by our values: (e.g., patients first, teamwork, scientific rigor and curiosity)
- A collaborative, data-driven pre-IPO start-up environment where we inspire each other to always perform at our best and focus on advancing science that will help patients
- Learning and development resources to help you grow professionally and potential for advancement for stronger performers
- Competitive compensation (Base & Performance Bonus) and stock option package (equity in an early-stage company)
- Rich medical, dental, and vision insurance plans
- Health, Limited, and Dependent Care FSA; HSA with company contributions
- 401(k) with company matching
- Pre-Tax Commuter Benefits
- Paid Term Life and AD&D, STD, and LTD plans
- Employee Assistance Program (EAP)
- Generous company paid holidays and flexible PTO
- Flexible work schedule (on-site/hybrid)
- Kitchen stocked with a variety of healthy and delicious snacks and drinks

The salary range for this position is $150,000 – 190,000. Nuvig considers various factors when determining the base compensation, including market survey data, experience, qualifications, and geographic location, which means that the actual compensation will vary.

About Nuvig

Nuvig Therapeutics, Inc., headquartered in Redwood City, California, is a science-driven research and clinical development organization focused on fundamentally transforming how we approach and treat inflammatory and autoimmune diseases. Our first product candidate NVG-2089 is a recombinant, human IgG1 Fc fragment that has been engineered to target immunomodulatory Type 2 Fc receptors and modulate immune response. Additional efforts are focused on engineering full-length therapeutic antibodies to maximize their ability to control aggressive autoimmune diseases. Founded in 2021 by industry experts, Nuvig Therapeutics is well-supported by top tier investors, ensuring robust funding to drive our innovative research and clinical programs forward. Key investors include Novo Holdings, Platanus, Bristol Myers Squibb, Digitalis Ventures, and Mission BioCapital.

If your life and career ambitions are to advance transformative medicines that redefine treatment paradigms, please take a look at our job openings. If you think you would be a good fit for our team, please send your resume and a cover letter explaining how you can contribute to Nuvig to careers@nuvigtherapeutics.com.