Job Description

Vice President, Regulatory Affairs

Why Nuvig

Be a part of a potential game-changer for patients with autoimmune disease! Nuvig Therapeutics is developing drugs that use one of the body's natural mechanisms for re-balancing the inflammatory response in chronic autoimmune disease. This mechanism should be active in a range of autoimmune diseases, without the inherent side effects and safety concerns that accompany long-term treatment with existing therapies that can make patients immunocompromised, or at risk for cancer. As one of the initial employees in a pre-clinical stage, growing company, this is an opportunity to earn an early equity position and play a key role in the success of the organization. Join us in making a dramatic difference in patients' lives!

Position Summary

The VP, Regulatory Affairs will be responsible for providing global regulatory leadership to support the development and registration of Nuvig products; provide leadership and direction for the global regulatory aspects of Nuvig products, including developing long and short-term planning of regulatory projects that align with the company's business plan; and develop strategies to ensure effective achievement of regulatory/business objectives. In this role, they will lead the development and implementation of department policies and the management build-out of the regulatory and quality assurance teams. The Vice President, Regulatory Affairs will also support the CMO in fundraising and M&A activities. This position will report to the CMO.

Externally this individual will interface with outside regulatory agencies, corporate partners, and vendors regarding development, regulatory, and registration strategies.

Key Responsibilities

- Lead the regulatory function and enable rapid and successful product development and approvals
- Develop robust regulatory strategies, including input on development plans and study designs, Target Product Profiles, regulatory risk assessments, resource planning, and regulatory submissions/health authority interactions in collaboration with development teams and senior management
- Ensure successful implementation and execution of regulatory plans to support product advancement
- Act as primary contact with FDA and other regulatory authorities
- Provide strong cross functional leadership for regulatory submissions/Health Authority interactions (INDs, CTAs, etc.) in collaboration with multidisciplinary development teams
- Liaise and negotiate with global regulatory authorities as needed for all aspects pertaining to drug development, including resolution of key regulatory issues and to expediting approvals of products
- Build partnerships with senior leaders from other functions to ensure that strategic business goals are met through the sharing of knowledge and expertise
- Maintain awareness of the global regulatory environment and assesses the impact of changes on business and product development programs. Facilitate interpretation of global regulations
- Proactively manage critical issues, taking leadership for the regulatory contribution

- Develop and implement department policies, processes, and SOPs
- Provide regulatory due diligence assessments of new business opportunities as required
- Manage vendors and build an internal team in the context of overall company growth

Qualifications

- BA/BS Degree required in a health/life sciences or related field. An advanced degree is strongly preferred.
- Strong executive leadership skills and presence with experience in growing and leading a high-performance team of regulatory professionals
- Ability and interest in rolling up their sleeves to perform hands-on regulatory activities while simultaneously building the department to ensure successful scalability as the program grow.
- At least 10+ years of experience in the biotechnology or pharmaceutical industry and 5+ years managing direct reports.
- Demonstrable track record of successful filings (IND/CTA, NDA/BLA/MAA) in US and ex-US jurisdictions (e.g., EU, AU, etc.) and developing and implementing complex regulatory strategies
- Demonstrated proficiencies in leading successful health authority meetings and interactions
- Experience in rare/orphan drug development
- Ability to thrive in a fast-paced, entrepreneurial environment, working collaboratively as well as independently under broad strategic guidance
- Ability to create and manage detailed timelines across disciplines and territories
- Strong negotiating skills and ability to think creatively and develop creative solutions
- Strong personal and interpersonal skills, including the ability to relate to and negotiate with others while acting with integrity and credibility to build trust
- Ability to take a hands-on role, prioritize and handle multiple projects simultaneously
- Superior analytical and problem-solving skills, with demonstrated intellectual and analytical rigor.
- Proven ability to effectively prioritize and handle multiple tasks in a fast-paced startup environment.
- Excellent written and oral communication skills
- Strong interpersonal skills and ability to work with others in a positive, collaborative manner.
- The highest level of integrity. Committed to the values of accountability and transparency, with a passion for scientific rigor and making a positive difference in patients' lives.

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
- Paid Term Life and AD&D, STD, and LTD plans
- Employee Assistance Program (EAP) and Travel Assistance Program
- Generous company holidays, sick time, and flexible PTO
- Flexible work schedule (on-site/remote or hybrid)
- Kitchen stocked with a variety of healthy and delicious snacks and drinks
- Free electric car charging on site

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About Nuvig

Nuvig Therapeutics, Inc., headquartered in Redwood City, CA 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 is a recombinant protein that selectively activates a class of immune regulatory receptors that are involved in rebalancing immune function following inflammation. Additional efforts are focused on engineering full-length therapeutic antibodies to maximize their ability to control aggressive autoimmune diseases. The company was founded in 2021 by veterans in this industry and closed a $47 million Series A financing, led by Novo Holdings A/S and Platanus, joined by Bristol Myers Squibb, Digitalis Ventures, and Mission BioCapital.

At Nuvig, we believe that a diverse, open, and inclusive environment and culture is key to our success. We will not be influenced in recruiting, hiring, promoting or any other employment practices by race, color, citizenship status, national origin, ancestry, sex, sexual orientation, gender identity/expression, age, religion, physical or mental disability, medical or genetic condition, marital status, veteran status, or any other characteristics protected under applicable federal, state and local laws. Nuvig will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable laws.