Job Description

Director, Regulatory Affairs

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

The Director, Regulatory Affairs will be responsible for developing and implementing global regulatory strategies encompassing clinical, non-clinical and CMC disciplines in support of investigational studies. This individual will be a key member of project teams and reports to the Head of Regulatory Affairs. The Director, Regulatory Affairs will be responsible for assuring the regulatory strategy is aligned with Health Authority requirements and regulatory submissions are on time and of high quality.

Responsibilities

- Lead program teams in preparing regulatory submissions including briefing documents, IND/CTA filings
- Oversee preparation of responses to all regulatory authority queries
- Manage critical clinical regulatory timelines and work with team members to resolve issues related to non-clinical studies, and clinical development and work in partnership with the CMC team. Serve as primary regulatory representative (for assigned projects) at internal meetings as well as at meetings with regulatory agencies for all clinical related issues
- Maintain detailed knowledge of global regulatory environment relevant for cell therapies and regenerative medicine including accelerated review programs. Communicate changing regulatory agency requirements; support pertinent regulatory intelligence per needs of programs
- Collaborate with external consultants, clinicians, CROs to provide regulatory guidance
- Escalate issues to Management that affect registration, regulatory compliance and continued lifecycle management of the product.

Knowledge and Skill Requirements

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- Strong knowledge of eCTD elements and structure and regulatory writing skills
- Demonstrated knowledge of regulatory requirements in the design and conduct of clinical trials, including preparation of regulatory submissions
- Experience with Orphan Drug Designation and BTD is preferred
- Effective and efficient written and oral communication skills
- A minimum of a Bachelor's and or undergraduate degree in a scientific discipline is required. Advanced degree is a plus
- 10+ years of biopharmaceutical industry experience with at least 8 years in regulatory affairs
- Knowledge of FDA and EU regulations is required. Experience in filing regulatory submissions from early development is a must. Experience with pre and post approval submissions and product lifecycle management is a plus
- Experience in biologics is preferred

- Ability to work in a fast-paced, start-up environment
- Experience directly writing submission documents that support clinical trials, marketing applications, and lifecycle management is highly preferred.
- Strong attention to detail with the ability to multi-task and handle multiple responsibilities simultaneously
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines
- Ability to work independently and as part of a team

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 $215,000 to $230,000. 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 Menlo Park, 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@nuvigtx.com.