



### **Job Description - Vice President of Clinical Development -**

WavoDyne Therapeutics is a newly founded pharmaceutical company based in Rochester, New York. The company is committed to developing novel therapeutics for patients suffering from cognition and memory impairment associated with neuroinflammation and neurodegeneration. The core technology of WavoDyne is a novel class of small molecule kinase inhibitors that are licensed from the University of Rochester Medical Center (URMC). WavoDyne's primary objective is to advance its leading drug candidate URMC-099 to Phase 2 clinical development for the treatment of Postoperative Cognitive Dysfunction (POCD) and HIV Associated Neurocognitive Disorders (HAND).

The company is recruiting for a Vice President of Clinical Development who will be responsible for spearheading these clinical development efforts.

#### **Summary/Scope:**

The Vice President of Clinical Development will be instrumental in supporting the progression of the company's lead drug candidates through all phases 1 of clinical development. The incumbent will have full responsibilities in designing and executing clinical trials, running programs focused on targeted therapeutic indications, and collaborating with key internal stakeholders, external stakeholders including CROs, and key opinion leaders.

#### **Core Responsibilities:**

- Design and optimize clinical trials and ensure clinical trials meet ethical and regulatory standards.
- Lead the development of the clinical protocol, including interactions with discovery, safety, marketing, regulatory, research and other functions.
- Write protocols that are in-line with the overall indication strategy.
- Present at Investigators' meetings.
- Conduct medical review and interpretation of efficacy and safety data from clinical trials.
- Have responsibility for the quality, coordination, medical accuracy and timeliness of clinical study reports.
  
- Assist senior management to oversee quality, coordination and timeliness of clinical sections of INDs, Investigator Brochures, CTAs, ISS's, ISE's, and clinical expert reports.
- Work with other WavoDyne Therapeutic team members or designated consultants to prepare abstracts, manuscripts and presentations for external meetings as well as author clinical sections of regulatory documents (IB, IND sections).
  
- Present and discuss data and findings at relevant team, governance, KOL and regulatory meetings.
- Establish and maintain working relationships with Study Investigators, KOL, academicians, and other Key Stakeholders.
- Ensure adherence to GCP/ICH and WavoDyne's Standard Operating Procedure (SOP) standards.
- Maintain clinical and scientific awareness in area of expertise.
- Guide and influence the distribution and management of Clinical Research Scientists.

- Manage lifecycle requirements and plans for designated indications.

**Qualifications****Prerequisites:**

- Minimum M.D. or PhD degree and substantial medical/clinical training in neurology or a related field.
- Minimum of 5 years of experience in designing, leading and managing significant clinical trials in neurology or neurodegenerative diseases.
- Direct industry experience is preferred; substantial experience working on industry-sponsored trials will be considered.

**Key Requirements/Knowledge:**

- Demonstrated understanding of drug development process.
- Knowledge of Good Clinical Practices (GCP), FDA regulations and guidelines, and applicable international regulatory requirements.
- Experience in designing clinical trial strategies to obtain regulatory approval.
- Ability to provide scientific and clinical expertise to a clinical development program and evaluate scientific and clinical strategies for a product.
- Ability to develop and evaluate strategies for the clinical development of a designated indication and to critically evaluate outside expert advice.
- Experience in clinical project planning.
- Experience working on global and complex clinical trials.
- Experience working effectively in a team/matrix environment.

**WavoDyne NeuroTherapeutic's Leadership Competencies:**

- Drive Innovation
- Shape Strategy
- Attract and Develop Talent
- Promote Open Communication
- Create Global Mindset
- Demonstrate Adaptability
- Foster Risk Taking
- Cultivate Teamwork

**Competencies /Skills:**

- Strong scientific/technical skills
- Strong interpersonal capabilities and ability to build networks
- Ability to anticipate and resolve problems
- Ability to lead cross functional efforts and teams
- Excellent verbal communication and technical writing skills
- Ability to present clearly using scientific and clinical terminology
- Effective communication skills to convey knowledge to people in different functions
- Sound organizational skills
- Possesses sense of urgency and can take initiative
- Ability to motivate team members
- Project management skills and focus on delivery of results

WavoDyne Therapeutics is committed to equal opportunity in the terms and conditions of employment for all employees and job applicants without regard to race, color, religion, sex, sexual orientation, age, gender identity or gender expression, national origin, disability or veteran status.

WavoDyne NeuroTherapeutics complies with all applicable national, state and local laws governing nondiscrimination in employment as well as employment eligibility verification requirements of the Immigration and Nationality Act.

All inquiries will be treated confidentially.

**Contact:**

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