Director, Clinical Development – GeoVax Labs, Inc.
(Consultant, Leading to Potential Full-time Position)

GeoVax is seeking a highly capable, motivated, experienced professional capable of leading the clinical development of oncology/immuno-oncology and infectious disease vaccine programs in support of regulatory registration and post-marketing clinical development.

Position Summary:

The Director, Clinical Development, working with the Chief Medical Officer (CMO), creates the overall program strategy for early development/first-in-human through late-stage clinical studies and life cycle management with responsibility for the development, conduct/implementation and reporting of the clinical study portfolio alongside the Clinical Operations team, including external CRO partners.

The incumbent works closely with cross-functional leadership that includes R&D, Clinical Operations, Regulatory, Medical Affairs, and Commercial to ensure that the Clinical Development scientific and medical strategies are aligned with broader corporate objectives and patient needs. He/She closely collaborates with experts in the field to ensure patient voice, clinical and value impact, and regulatory inputs are incorporated. He/She is expected to have a strong commitment to achieving corporate objectives while maintaining the highest ethical, regulatory and scientific standards. This role reports to the CMO.

Critical roles and activities:

- Serve as a key leader in the organization and provide clinical development advice and strategy working with the FDA and other regulatory bodies;
- Create proven clinical development strategist with experience designing, implementing and conducting clinical trials; knowledge of and ability to implement multiple types of trial designs;
- Ensure the development of scientific content of clinical documents such as protocols, informed consent documents, final study reports, and submissions (e.g., annual reports) according to the agreed upon project timeline, working in a close, cross functional and external collaborative manner; oversee and manage the selection of and ongoing activities of CROs;
- Work effectively across functions, particularly when interfacing with clinical operations, CMC, medical affairs, pharmacovigilance, and regulatory affairs.
- Maintain and develop relationships with key opinion leaders, clinical investigators, patient advocacy, outcomes experts, and other instrumental external stakeholders.
- Execute and deploy drug development strategic plans, develop contingency plans, provide technical and strategic advice, and meet milestones and budgets.
- Provide insight to pipeline determination in clinical feasibility and translate findings from research and nonclinical studies into clinical development opportunities.

- Provide clinical leadership and work in a team environment in interactions with external stakeholders and internal stakeholders.
- Provide medical support as needed on company and non-company sponsored studies, non-interventional studies and investigator sponsored studies.
- Critically read and evaluate the relevant medical literature; know the status and data from competitive products; and keep updated with medical and other scientific developments relevant to the product.

Qualifications:

- Clinical trial development professional with a strong pharmaceutical/vaccine development and clinical experience, especially overseeing CRO relationships and activities;
- Experience in Oncology/Immuno-oncology and/or Infectious Disease vaccines (preferred);
- US and Ex-US regulatory and clinical trial conduct experience (preferred);
- At least 7+ years of experience in a clinical research role in the biopharmaceutical industry, with significant role in managing/overseeing CRO activities;
- Possess an understanding of applicable US and EU drug development regulations, ICH, and cGCP regulations

Knowledge, Skills and Abilities:

- Strategic leadership and communication skills, strong initiative, ethics, and judgment, and demonstrated ability to positively represent the company
- Experience with leading early and late-stage clinical trials, regulatory filings, and product launches in their respective areas of oncology/immuno-oncology or infectious disease vaccines;
- Demonstrated ability to develop and maintain excellent working relationships with both internal colleagues and external contacts, including key thought leaders, and investigators
- Ability to collaborate with scientific/technical personnel, commercial and medical affairs
- Ability to think critically, and demonstrated troubleshooting and problem-solving skills
- Comfortable in a fast-paced company environment and able to adjust workload based upon changing priorities
- Exceptional interpersonal, problem-solving and written and verbal communication.
- Excellent written and oral communication skills, including presentation skills