200 Clarendon Street, 17th Floor
Boston, MA 02116

Position Title: Vice President of Medical Support

About AZTherapies: Extending Brain Health

AZTherapies is an advanced clinical-stage biopharmaceutical company developing novel therapies that aim to fundamentally change neurodegenerative disease progression, extending normal cognition and function and improving quality of life in the aging population. Advancing a growing pipeline of candidates to treat patients with few therapeutic options, our lead program, ALZT-OP1, is built on a multi-modal approach that recognizes neuroinflammation as a root cause of serious neurodegeneration and seeks to stop or slow the progression of disease. Our Phase 3 COGNITE trial in early Alzheimer's disease is fully enrolled, with expected study completion later this year. Following our lead program, we are advancing candidates for the treatment of amyotrophic lateral sclerosis (ALS), post-ischemic stroke cognitive impairment, and other indications. Our company is also developing a platform of Chimeric Antigen Receptor (CAR) engineered T regulatory cells (CAR-Treg) to shut down neuroinflammation and treat neurodegenerative diseases. AZTherapies is a private company headquartered in Boston, Massachusetts.

An Exciting Opportunity in a Fast-growing Organization

The Vice President of Medical Support will be responsible for providing scientific and medical support for product development, quality systems and regulatory affairs. The position requires professionalism and discretion, the ability to multi-task while delivering high quality work, and the capability to work effectively in a rapidly changing environment. The role will interact closely with all levels of management and staff, as well as outside service providers (vendors, consultants, etc.).

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Provide support for Clinical Research and assist in the writing, reviewing and medical oversight of clinical trials:
    - Lead the creation of clinical protocols.
    - Lead the creation of investigator brochures (IBs), clinical study reports, and documents dealing with INDs, NDAs, supplements and amendments.
    - Medical monitoring for clinical trials as designated.
    - Respond to medical questions relating to the clinical trials, from other departments, study sites, authorities and/or other external entities relevant to the trial in question.
    - Ensure the medical and scientific quality of clinical trial protocols and clinical trial reports
    - Medical lead supporting Data Safety Monitoring Board (DSMB)
    - Provide safety review during clinical trial execution including review of safety information and provision of applicable recommendations.
    - Work closely with 3rd party pharmacovigilance to ensure safety oversight for all clinical trials.
    - Evaluate adverse events, serious adverse events (SAEs) and safety reports.
    - Review SAEs submitted from the sites to determine the causality of the event and the relationship of the event to the study product.
    - Review the scientific and medical sections of all publications of clinical trial results.
    - Provide scientific and clinical input to study-related documents and analysis plans including Informed consent forms (ICF), statistical analysis plans (SAP), clinical pharmacology analysis plans (CPAP), and clinical study reports (CSR).

- Provide Medical Support for Regulatory Affairs and R&D Activities.
    - Provide medical support for regulatory filings.
    - Medical department subject matter expert

Qualifications:

- Medical Degree (MD)
- At least 5 years of basic or clinical research experience in an academic or industrial setting, with experience in analysis of research data and publications; working knowledge of biostatistics and pharmacokinetics; working knowledge of GCP, scientific and clinical research methods, regulatory affairs, and clinical study design.
- NDA experience a plus
- Global clinical research experience and experience interacting with regulatory authorities is a plus
- Understanding of domestic and international regulatory requirements.

Competencies:

- The ability to adapt and work effectively within a variety of situations; adapts to organizational priorities and changes in job demands.
- Builds productive working relationships across a diverse spectrum of departments.
- Ability to handle multiple responsibilities simultaneously and meet high quality and timeliness standards.
- Excellent oral and written communication skills
- Ability to effectively prioritize and manage multiple projects and tasks.
- Possess a flexible approach to problem solving.
- A team player, who listens effectively and invites response and discussion.
- A collaborator who communicates in an open, clear, complete, timely and consistent manner.