VICE PRESIDENT, CLINICAL OPERATIONS
POSITION DESCRIPTION

Job Title: Vice President, Clinical Operations

Reports to: CMO

Classification: Full-Time, Exempt, Salaried

Company Summary: Aeglea BioTherapeutics, Inc. is an Austin, TX based biotechnology company committed to developing engineered human enzymes for the treatment of rare diseases and cancers associated with abnormal amino acid metabolism. The company's recombinant human enzymes are designed to degrade specific amino acids in the blood in order to reduce toxic levels of amino acids in in rare diseases or to starve tumors dependent on amino acids by reducing levels below the normal range. Aeglea's clinical program for its lead product candidate, AEB1102, includes three recently initiated Phase 1 clinical trials, studying AEB1102 for the treatment of patients with Arginase I deficiency as well as patients with solid tumors or hematological malignancies. The company is building a pipeline of additional product candidates targeting key amino acids, including AEB4104, which degrades homocysteine, a target for an inborn error of metabolism, as well as two potential treatments for cancer, AEB3103, which degrades cysteine/cysteine, and AEB2109, which degrades methionine.

Position Summary: Aeglea BioTherapeutics, based in Austin, Texas, is actively recruiting for a VP of Clinical Operations, accountable for the resourcing, development, training and management of a successful clinical operations team.

Essential Duties and Responsibilities: Duties include but are not limited to:

- Create, execute and proactively manage clinical trial processes.
- Provide leadership, strategic oversight, and guidance of Clinical Operations to ensure quality, timeline, resources and budget goals are met.
- Establish performance indicators and apply to ensure the successful execution of clinical trials to agreed timelines
- Ensure the effective and constructive integration of clinical operations knowledge and expertise into all applicable Clinical Development activities including integrated development plans and study protocols at Aeglea; interact and collaborate with other department heads as appropriate.
- Represent all aspects of Clinical Operations and provide updates as required to the Executive Committee, Project Teams, Board of Directors and other key internal stakeholders.
- Lead & mentor Clinical operations staff to support successful internal training and its implementation and serve as an advocate for professional development of Clinical Operations staff.

- Oversee, plan and implement Quality Checks for clinical projects and provide leadership and direction to ensure the highest standards for compliance with Company SOPs, ICH-GCP guidelines, Regulatory authority regulations and patient safety standards
- Mentor clinical operations staff on the Regulatory Inspections process and develop a pro-active approach for Inspection readiness
- Assist the QA department in the development, review and updating of Aeglea clinical SOPs
- Accountable for the authorship of operational sections of protocols and investigator brochures, and leading the identification of and interaction with investigative sites and investigators, including study execution.
- Develop and maintain strong relationships with CROs, external experts and Investigators to ensure effective execution of internal and external clinical projects.
- Coordinate with the VP of Biometrics to deliver high quality data deliverables on time and on budget (e.g. development of case report forms, collaboration with statisticians, collaboration with data managers, data overview, clinical study reports, etc.)
- Provide support for regulatory submissions, supporting dossier development and participating in interactions with FDA, EMA and other regulatory agencies.
- Keep abreast of competitive regulatory and clinical practices and utilize this knowledge during the ongoing development and adjustment of plans.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required or desirable.

Education/Experience: The ideal candidate will require:

- Bachelors in Life Sciences, Nursing Licensure or Pharmacy; an advanced degree (MS or PharmD) is preferred.
- A minimum of 15 years of experience with expertise in the areas of clinical operations development and strategic planning; developing, implementing, and leading early to late stage clinical trials.
- In-depth understanding and experience across the clinical operations value chain, with a track record of success in study planning, execution, data cleaning, database locking, study report generation and regulatory inspection. Therapeutic experience in genetic rare diseases and/or Hematology/oncology coupled with experience with pivotal, multi-site clinical trials is highly desirable.
- Experience with global drug development and NDA filing is preferred; experience in developing protocols, SOPs, Clinical Study Reports, INDs, NDAs, as well as other clinical, regulatory, and safety documents preferred.
- Experience with clinical data management and pharmacovigilance is a plus.

Knowledge, Skills and Abilities:

- Expertise in clinical operations – demonstrated ability to effectively manage projects and people. Proactive problem solving abilities and follow-through
- Strong communication and presentation skills-demonstrates strong written and verbal communication skills and ability to relay vision/strong sense of department organization,

processes, and change to management and staff

- Experience leading a rapidly changing organization and integrating new personnel is essential, as well as ability to evaluate and resolve complex problems
- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical trials, clinical study design, and data management methods. Self-motivated to maintain expertise in regulatory requirements and guidance to ensure that the Clinical Operations remains compliant with GCP and other global regulatory guidelines or laws
- For the best fit, you should be a results-oriented team player with strong interpersonal and communications skills, capable of working collaboratively with colleagues

Work Environment:
This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally on occasion is required, it is anticipated that this will be less than 20% of work time.

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.