ASSISTANT CLINICAL OPERATIONS SPECIALIST
POSITION DESCRIPTION

Job Title: Assistant Clinical Operations Specialist

Reports to: Clinical Operations Specialist

Classification: Full-time, FLSA Non-exempt, Hourly

Company Summary: Aeglea BioTherapeutics, Inc. is a biopharmaceutical company based in Austin Texas developing novel treatments for inborn errors of metabolism and cancers. Aeglea BioTherapeutics, Inc was founded in 2013 to develop engineered human enzymes invented in the laboratory of George Georgiou, Ph.D. at The University of Texas at Austin. The Aeglea BioTherapeutics product pipeline consists of a suite of amino acid degrading enzyme treatments including AEB1102, AEB3103, AEB2109 and AEB4104. Please see www.aegleabio.com for more information.

Position Summary:

The Assistant Clinical Operations Specialist is responsible for providing trial document and systems management support to Clinical staff throughout trial startup, maintenance and closeout periods, reporting to the Clinical Operations Specialist. The Assistant Clinical Operations Specialist will liaise with other Aeglea personnel, as determined by the Clinical Operations Specialist, to ensure all trial documentation is filed appropriately and all trial systems are maintained in accordance with company SOPs, Good Clinical Practice, ICH Guidelines and all other regulatory requirements.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following:

- Assist in the collection, review and approval of country specific and/or site-specific documents and/or essential regulatory documents with high quality.
- Upload and/or QC study documents to electronic Trial Master File (eTMF).
- Assist in the preparation and submission of IRB/EC application until final approval received from investigator.
- Manage input of study contact and other data as required within the Clinical Trail Management System (CTMS).
- Maintain a working knowledge of, and ensure compliance with applicable ICG-GCP Guidelines, local regulatory requirements, and Aeglea SOPs and study specific procedures.
- Assist with the QC/audit of the eTMF and other central files and liaise with Clinical Team personnel as required.

- Take minutes of project meetings as required.
- Other duties as assigned.

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.

Education/Experience: The ideal candidate will offer:

- Bachelor's degree in business or life sciences preferred; Associates degree and/or equivalent work experience may be substituted for a BS degree
- At least 4 years of prior administrative or office management experience required
- Prior biotech and/or clinical trial experience preferred

Knowledge, Skills and Abilities:

- Read, write and speak fluent English; excellent verbal and written communication skills
- Ability to apply common sense understanding to carry out instructions furnished in written, oral, or diagram form
- Excellent critical thinking skills and strong attention to detail required
- Basic knowledge of clinical research preferred
- Ability to deal with problems involving several concrete variables in standardized situations
- Intermediate to advanced knowledge of Microsoft Office Suite and email
- Demonstrated ability to take initiative and work independently
- Work with the sense of urgency in completing assigned tasks
- Basic understanding of time management in order to meet daily metrics or team objectives
- Shows commitment to and performs consistently high quality work
- Flexibility towards work assignments and new learning as required
- Basic negotiation and diplomacy skills

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.

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.