



SENIOR DIRECTOR, CMC POSITION DESCRIPTION

Job Title: Senior Director, CMC
Reports to: Vice President, Manufacturing
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 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 homocystine, a target for an inborn error of metabolism, as well as two potential treatments for cancer, AEB3103, which degrades cysteine/cystine, and AEB2109, which degrades methionine.

Position Summary: Aeglea BioTherapeutics based in Austin Texas, is actively recruiting for a Senior Director of CMC. The Senior Director of CMC is accountable for establishing the CMC development plan and leading the execution of the plan for drug substances and drug products from pre-clinical through commercial development.

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

- Establish, manage and lead the CMC development plan for drug substances and drug products from pre-clinical through commercial development
- Select third-party manufacturers working with Quality and Regulatory, negotiate effective supply/technical agreements. Identify contract analytical laboratory sites required to guide and support third party manufacturing relationships
- Direct/oversee contract manufacturing, testing, packaging and labeling operations for the company's drug substances and drug products. Act as primary liaison with contractor(s) on assigned projects. Guide external operations through tech transfer, process and method development, optimization, qualification and validation of the activities related to all manufacturing operations
- Participate in product development project teams as CMC functional area representative
- Working with Quality Assurance, develop SOPs and guidelines related to the production,

planning, disposition and management, materials, etc.

- Work with Regulatory, QA and Senior Management to ensure that all company policies are adhered to and all external manufacturing activities comply with relevant regulations
- Maintain knowledge of current best practices of biological manufacturing. Identify emerging trends and technologies and lead implementation/feasibility assessment, as appropriate
- Design and execute the development plan to support global submissions
- Prepare CMC regulatory filing sections (domestic and international) working with Regulatory and Quality
- Review and approve master and executed batch records from all manufacturing activities; analytical release testing, stability studies and investigations, as required
- Develop production plans to support preclinical, clinical, and commercial development and adjust plans as appropriate to meet corporate objectives
- Provides comprehensive project analysis to senior management as required in the form of reports or presentations as needed

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:

- BS/MS or PhD in a relevant discipline
- A minimum of 10 years of experience in CMC project management, development, scale-up and clinical/commercial development and manufacturing in the biotechnology or pharmaceutical industry
- Experience in leading and direct management of research, process development, and manufacturing
- Extensive experience in leading biological process and analytical development
- Experience in achieving regulatory approval of new drugs or biologicals

Knowledge, Skills and Abilities:

- Good understanding of cGMP and FDA regulations and guidelines relating to CMC-related areas
- Knowledge of global CMC-related regulatory requirements and guidelines an advantage
- Excellent leadership, managerial and communications skills in a cross-functional environment
- Proficiency in analysis of scientific data and results with ability to review scientific documents including reports, publications and regulatory submissions
- Prepared and managed the preparation of CMC regulatory filings

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 10-15% 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.