

Position: Vice President, Clinical Development, Ophthalmology

Reports to: Chief Medical Officer

Location: Lexington, MA

Company Summary:

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for proliferative vitreoretinopathy and other retinal diseases, post-transplant lymphoproliferative disease, autoimmune disease, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

Position Summary:

The Vice President, Clinical Development, Ophthalmology, will report directly to the Chief Medical Officer. He/she will be responsible for all day-to-day aspects of Aldeyra's ocular clinical drug development programs, including the three indications of Reproxalap Ocular. He/ she will work in crossfunctional teams to assure the highest standards of clinical drug development. This person will be responsible for all medical aspects of regulatory communications documents, as well as the medical review of ocular clinical trial data. The Vice President, Clinical Development, Ophthalmology will work alongside the Vice President, Clinical Development, Non-Ocular Programs.

This individual must be able to communicate both verbally and in writing his or her medical expertise to guide the development and execution of clinical development plans, protocols, abstracts, and clinical trial reports for Aldeyra's ophthalmic clinical programs. This will involve a deep knowledge and understanding of Aldeyra's Standard Operating Procedures, medical monitoring and the monitoring of competitor activities and data. He/she will serve as the key individual providing medical expertise and input into, including authoring of, the clinical development plans, protocols, abstracts, and clinical trial reports for all ophthalmic candidates. He/she will also contribute to pharmacovigilance review of clinical trial data as well as collect external data and competitive intelligence in select aldehyde targets.

Furthermore he/she will give clinical input in development activities related to Aldeyra's pipeline and will serve as an internal resource for all Aldeyra functions requiring clinical input. For the right individual with the interest and/or experience, there will be an additional opportunity to oversee the ocular clinical operations team at Aldeyra.

Responsibilities:

 Directing the development, presentation and publication of clinical data on the company's ocular therapeutic candidates, ensuring the highest quality and consistency with corporate strategy;

- Medical monitoring, coding and data cleaning together with clinical operations;
- Medical writing of clinical sections in regulatory documents not limited to IND submission, IND annual updates, briefing documents, study protocols, investigator brochures and other study-relevant documents like patient informed consent documents;
- Manuscript writing of publications or other documents intended for external audiences;
- Supervision of external consultants if applicable;
- Primary point of contact for ocular clinical trial staff at study sites, as well as for regulatory, safety and clinical operations and other functions requiring clinical input;
- Review safety data for clinical detection and prepare safety charters, DMC charters, or other specific management plans or manuals in a cross-functional team if not primary author;
- Support or preparation of data interpretation and clinical trial reports;
- Together with Clinical Operations preparation of Investigator Alert letters and SAE reports as required; and, Medical affairs activities as needed for the ophthalmic programs.

Education & Experience:

The desired candidate will likely possess an M.D. and/or Ph.D., though this is not a definitive requirement of the candidate. It is understood, that education, while an important index of achievement, orientation, and intellectual capacity, will not serve as the primary variable in this decision process. Personal characteristics, common sense, work ethic, and demonstrated accomplishment in business and corporate development will serve as key components in the evaluation of candidates.

In terms of professional experience, we are seeking an individual who should possess significant experience in clinical development with publication in peer-reviewed journals. This person must have knowledge of clinical development, the FDA, international global clinical trial regulations and good clinical practices (GCP) guidelines. Preference will be given to candidates who have previous experience with drug development within the pharmaceutical or biotechnology industry, particularly at companies addressing ophthalmology.

Qualities & Characteristics:

- Flexible and adaptable style with a willingness and eagerness to take on challenges;
- Entrepreneurial spirit with the ability to take risks;
- Ability to work as a true team player and be effective in a collaborative culture;
- Strong leadership and motivational capabilities;
- Personal versatility and flexibility as the program and team evolve;

- Ability to instill and quickly earn trust among teams;
- Complex thinker who has the ability to articulate options for ambiguous situations and the confidence to make decisions with authority and with full understanding of potential outcomes;
- Ability to anticipate adverse scenarios and provide contingency plans to address them
- Excellent communication skills, both oral and written.

To Apply:

Please email your cover letter and resume to info@aldeyra.com or to send a resume via an alternative method, please mail it to our corporate address:

Aldeyra Therapeutics, Inc. Attention: Human Resources 131 Hartwell Avenue Suite 320 Lexington, MA 02421