Position: **Clinical Scientist**
Reports to: **Vice President, Clinical Development**
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 primary responsibility of the Clinical Scientist is to provide technical support to one or more clinical programs to ensure the successful design and implementation of Clinical Development plans. Main responsibilities include supporting the Medical Lead on clinical trial design, medical and safety monitoring, including the ability to analyze and synthesize assessments and information as it relates to study conduct and/or subject safety, clinical data analysis, and contributing to regulatory submissions, publications, and presentations.

Experience and essential skills:
- Contribute to the planning and design of clinical studies, in addition to the development of clinical plans in accordance with corporate objectives
- Contribute to the clinical oversight and medical review of clinical trial data in collaboration with the Medical Lead and/or Medical Monitor during the conduct of the study
- Based on program and resource needs, the clinical scientist may assume the operational leadership for certain studies
- Work in close collaboration with Clinical Operations to ensure translation of the clinical protocol into operational deliverables, including but not limited to performing ongoing review and analysis of clinical study data and preparing/reviewing study plans (i.e., Medical Monitoring, Medical Data Review, Safety Management, etc.)
- Contribute and coordinate the writing and revision of clinical documents, such as study protocols, clinical study reports, investigator brochures, and other materials for regulatory submission
- Contribute to responses pertaining to clinical questions from regulatory agencies and/or ethics committees
- Establish good working relationships with external scientific advisors, thought leaders, clinical investigators, and clinical vendors

- Perform literature searches and critically review and summarize the relevant scientific, drug development, and medical literature to support the development of clinical and/or regulatory documents
- Support preparation of scientific material for conference presentations or publications
- Contribute to the development of SOPs and associated guidelines and templates
- Monitor departmental compliance with required training and adherence to all corporate and departmental SOPs, GCP/ICH guidelines and QC/QA procedures

Qualifications:

Required

- Advanced degree in a scientific discipline
- 10+ years of biotech/pharmaceutical/clinical experience and knowledge of the drug development process with 5+ years in clinical
- Experience working with medical monitors, R&D functions, regulatory affairs, quality assurance, thought leaders, and clinical investigators
- Excellent communication (oral and written), analytical, organizational, and project management skills
- Ability to think strategically and creatively, function independently, deliver on timelines, have strategic insights and have detailed knowledge of the activities, and procedures involved in clinical drug development
- Strong ability to work collaboratively in a matrix environment and can foster relationships
- A thorough understanding of ICH, GCP, and relevant regulatory requirements
- Ability to travel 20%

Desired

- Doctorate-level degree
- Experience with global clinical studies
- Experience with inflammatory diseases, oncology, rare diseases, ophthalmology, and/or dermatology clinical studies
- Demonstrated expertise with developing and implementing biomarkers and translational medicine strategies in early and late stage clinical development and mechanistic profiling programs
- Experience with regulatory submissions