Position: **Associate Director/Director of Analytical Development and Quality Control**
Reports to: **Senior Director, CMC**
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 Associate Director/Director of Analytical Development and Quality Control will report directly to the Senior Director of CMC. In this role, you will be responsible for leading the AD/QC aspects for all programs (early- and late stage) at Aldeyra. You will work with multiple contract organizations including CMOs and Contract Laboratories to ensure appropriate analytical development approaches are followed, and appropriate ICH and regulatory quality standards are met during development and commercial stages. You will collaborate closely with cross-functional departments to achieve corporate goals and objectives.
Proficiency in Quality Control execution and systems, stability study programs for multiple product configurations, method development, qualification, and validation in support of IND, IMPD, and NDA filings will be required. We are interested in a self-starter with the ability to work independently under minimal supervision and who is seeking to be part of an authentic, innovative, and fast-paced team.

Key Responsibilities: :
- Development and qualification of cGMP analytical methods for lot release and stability testing of products
- Oversight and management of CRO/CMO engaged in AD and QC activities. Provide technical review of analytical data integrity and laboratory documentation, method development reports, and method validation protocols/reports.
- Author, update and revise CMC regulatory filing sections to support regulatory filings.
- Ensure compliance with cGMP in a manufacturing environment such that products are assessed against agreed-upon specifications promptly to support in-process, lot release, and stability testing.
- Maintain stability project plans and their associated timelines, including readiness of sampling plans, and coordinate with technical operations to ensure sample availability for stability studies.
- Perform deviation investigations and CAPA implementation in support of CMC QC projects and continuous improvements.
- Support inspections/audits (regulatory and internal) and draft audit observation responses related to AD and QC.
- Responsible for planning, tracking, monitoring, and adherence to budget.
- Support stability program activities for drug substance (DS) and drug product (DP)/placebo from GLP

Toxicology to GMP manufacturing (Phase 1-3), including development stability programs to support process development, specification setting, IND-enabling and long-term stability programs, regulatory filings, change control, stability-related QC investigations.

- Contribute to the development of an operating model and continuous improvement of platforms based on analytical development plans for the complete product life cycle.

Qualifications:

- Master's degree in chemistry, analytical chemistry, or a related life science field; Ph.D. degree is highly desirable. A minimum of 10+ years in analytical development and quality control.
- Experience in the development, qualification, and validation of analytical methods to support various stages of drug development through NDA and commercialization.
- Experience working in the design, execution, and interpretation of effective accelerated stability and forced degradation studies to support potential excursions and understanding of product degradation pathway/s.
- Excellent oral and written communication skills, auditing skills, and a proven ability to work autonomously, manage effectively, and influence in a cross-functional, matrixed environment.
- Proficient in project management, excellent organizational skills, and able to concurrently work on multiple projects with tight timelines.
- A team player with great interpersonal skills, excellent verbal communication skills.
- Proficiency in MS Office, Word, and Excel; Proficiency in statistical analysis software is desirable.
- Ability to travel 20%

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