Position: **Regulatory Affairs Sr. Manager/Associate Director**
Reports to: **Vice President, Regulatory Affairs**
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 Regulatory Affairs Manager is responsible for supporting regulatory activities; coordinating and preparing documents for submissions; contributing to the completion of projects and ensuring compliance with required regulations and guidelines.

- Prepare and assemble clinical, preclinical and CMC information for submissions of INDs, NDAs, amendments, supplements, and annual reports
- Contribute to assessment of regulatory strategy
- Review the necessary pre-study documents with clinical operations for clinical trial execution (IRB approval, 1572 Forms, Financial Disclosure, etc.)
- Support the production, assembly and publishing of submission documents
- Coordinate submission related activities between departments
- Act as liaison to e-submission vendors
- Prepare meeting materials for meetings with FDA and other regulatory agencies
- Author/review departmental SOPs

Experience and essential skills:

- Bachelor's degree in scientific or related discipline (if required)

- A minimum of 6 years of industry experience with at least 3-4 years' experience preferred in pharmaceutical regulatory activities for senior manager or
- A minimum of 8 years of industry experience with at least 5-6 years' experience preferred in pharmaceutical regulatory activities for associate director
- Experience within the pharmaceutical industry and strong submission management experience and exposure to regulatory strategy is required.
- Ability to apply scientific knowledge or technical expertise to regulatory issues and product development.
- Strong organizational skills with the ability to manage projects and provide regulatory guidance/training to others in the department as needed.
- Proven ability to prioritize and multi-task with minimal supervision based on interactions with project ream members.
- Excellent written and oral communication skills, with writing ability to meet regulatory requirements and standards.
- Ability to communicate effectively and maintain effective working relationships.
- NDA/CTD/eCTD submission knowledge and exposure.
- Experience with Electronic Data Management and publishing systems.
- Proficiency in MS Office programs.
- Experience with SharePoint and StartingPoint are a plus.

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