Position: **Head of Regulatory Affairs**
Reports to: **Chief Medical Officer**
Location: **Lexington, MA**

Company Summary:
Aldeyra Therapeutics is developing 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 and other forms of ocular inflammation. The company is also developing other product candidates for autoimmune and metabolic diseases. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere. We are a publicly traded company on the NASDAQ exchange, **ticker** ALDX.

Position Summary:
This role is responsible for developing, directing and implementing the regulatory strategy and filings through oversight of a vendor responsible for the Regulatory Operations and submissions.

Responsibilities include:

- Function as liaison between major health authorities including the FDA, EMA and Health Canada and company for assigned projects.
- The planning, coordination, organization and preparation of complete high quality regulatory submissions for assigned products
- Ensuring regulatory compliance for all assigned responsibilities.
- Responsible for the implementation of regulatory strategies for the development and maintenance of assigned product or products.
- Maintain up-to-date knowledge and expertise of FDA regulations/guidance documents, and ICH guidelines
- Working actively with the project teams to position our programs for accelerated drug development anticipating challenges and implementing risk mitigation strategies.
- Representing the regulatory function on cross-functional development teams.
- Authoring and otherwise preparing responses to requests for information from regulatory authorities.

Experience and essential skills:

- 10+ years of regulatory experience within a pharmaceutical or biotechnology organization with a focus on developing strategy
- Orphan disease experience and small company experience preferred

- Experience in the oncology therapeutic area is preferred
- Experience working in a global regulatory environment presenting to the FDA and EMA
- Previous experience with successful regulatory submissions either hands on or developing strategy (e.g., IND, FDA pre-NDA/BLA, EOP2 meetings, advisory committee meetings and/or EU oral explanations/scientific advice,).
- Strong medical writing and communication skills and ability to work cross-functionally with both internal and external stakeholders