Position: **Associate Director/Director Toxicology**
Reports to: **Vice President, R&D**
Location: **Lexington, MA**

Company Summary:

Aldeyra Therapeutics is a biotechnology company devoted to improving lives by inventing, developing, and commercializing next-generation medicines that treat immune-mediated diseases. Aldeyra's lead product candidate, reproxalap is a small molecule RASP (Reactive Aldehyde Species that are Pro-Inflammatory) inhibitor in Phase 2b clinical development for the treatment of dry eye disease, and Phase 3 development for the treatment of allergic conjunctivitis, non-infectious anterior uveitis, and Sjögren-Larsson Syndrome. Aldeyra is also developing other product candidates for autoimmune and metabolic diseases.

Position Summary:

Due to its expanding pipeline, Aldeyra is seeking a Toxicologist to help advance our small molecule drug development candidates. The successful candidate must be able to work on multiple programs, and function effectively and independently in a collaborative, fast-paced environment.

The successful candidate will have a solid understanding of small molecule toxicology and safety assessments in multiple species such as rodents, canines and non-human primates, and following multiple routes of administration.

Responsibilities include:

- Plan, execute, and monitor toxicology programs from IND-enabling studies to NDA-enabling studies, including safety pharmacology, general toxicology, toxicokinetics, carcinogenicity, and DART. Assess and communicate plan risks.

- Proactively develop plans for toxicology programs.

- Work directly with contract research organizations (CROs) to request quotes, provide expertise during protocol development, monitor studies, and review, finalize, and archive study reports.

- Contribute to the preparation of nonclinical components of US and ex-US regulatory submissions. Must be able to write clear, high quality scientific and regulatory documents (e.g., INDs, CTAs, IBs, IMPDs).

- Collaborate with pre-clinical, clinical, CMC, and regulatory to ensure that safety and toxicology study designs support program goals, sufficient drug is available to conduct studies, and corporate timelines are met.

- Communicate study results to teams, as appropriate.

- Work with functional leadership to develop study timelines and budgets, and coordinate program activities.

Experience and essential skills:

- PhD in Toxicology or related field, or DVM; DABT preferred.

- Minimum four years of experience planning and executing safety and toxicology programs for small molecule programs and a broad understanding of the drug development process.

- Experienced in selection and management of external CROs.

- Excellent writing skills are essential.

- Proficient in the generation of scientific documentation to support regulatory submissions.

- Strong interpersonal skills, problem-solving, and organizational skills required.

- Strong knowledge of global regulatory guidance and GLPs.

- Must have the background and experience to interpret data from pharmacology, DMPK, toxicology, and pathology studies, and assess clinical relevance and potential impact.

- Experience with bioanalytical method development and validation is a plus.

To apply for this position, please email info@aldeyra.com