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

Director Toxicology and Pharmacology

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) inhibitor in Phase 3 clinical development for the treatment of dry eye disease, allergic conjunctivitis, non-infectious anterior uveitis, and Sjögren-Larsson Syndrome. Aldeyra is also developing other product candidates for autoimmune and metabolic diseases.

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. He or she will have a solid understanding of small molecule toxicology and safety assessments in multiple species, following multiple routes of administration.

Reporting to the VP of R&D, the ideal candidate will provide expert guidance on the design and implementation of nonclinical toxicology and safety studies, as well as pharmacology studies to evaluate efficacy, mechanism of action, to support our development programs.

<u>Responsibilities</u>

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.

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

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.

Prepare non-clinical 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).

Supervise the design, execution, interpretation, and reporting of pre-clinical pharmacology studies. Clearly communicate study results, as appropriate.

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

Requirements

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

Seven to ten years of experience in the pharmaceutical industry, planning and executing safety and toxicology programs for small molecule programs, and a broad understanding of the drug development process and regulatory requirements.

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

Experience in selection and management of external CROs.

Experience writing non-clinical sections of INDs, CTAs, IMPDs, and IBs to support regulatory submissions. Excellent writing skills are essential.

Strong interpersonal skills, including supervisory experience, problem-solving, and organizational skills required.

Strong knowledge of global regulatory guidance and GLPs.

Experience with bioanalytical method development and validation is a plus.

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