Position: **Senior Director Biostatistics**
Reports to: **Vice President, Clinical Development**
Location: **Lexington, MA**

Company Summary:
Aldeyra Therapeutics is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. The company's lead product, ADX-102, is an aldehyde trap in development for ocular and systemic inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism.

Due to Aldeyra's strong intellectual property position, our research has identified numerous potential targets including inflammatory diseases and diseases known an inborn errors of metabolism that result from genetic mutations in aldehyde-metabolizing proteins. Accordingly, we have developed a series of promising product candidates designed specifically to trap and mitigate the toxic effects of aldehydes.

We are a publicly traded company on the NASDAQ exchange, ticker ALDX.

Position Summary:
This role is responsible for developing and directing the biostatistical strategy and filings.

- Serve as biostatistics program lead for assigned compound(s) and/or study biostatistician, and provide strategic and technical leadership in the design, execution of clinical development plans, clinical trials, and statistical analysis plans.
- Analyzes complex data issues and readjust analysis plans according to statistical considerations
- Conducts complex statistical analysis utilizing SAS® and other statistical software packages, as required
- Manage and oversee external biostatisticians working on studies within his/her assigned compound(s) to insure timely and high-quality biostatistics deliverables.
- Monitor project progress and insure proper resource allocation for successful project deliverables against goals and timelines.
- Participate in planning for FDA/EMA meetings and preparation of associated responses.
- Perform quality control checks of statistical analyses and SAS programs, as needed.
- Work as part of a collaborative, cross-functional team with members from other disciplines.

- Be responsible for vendor management for statistical, programming, and database functions.
- Participate in other activities and meetings to support Biostatistics and the Development Team as necessary.
- Maintain up to date knowledge on development and paradigm shifts in biostatistical methodologies and implementation in drug development programs

Qualifications and Experience

- PhD.in Biostatistics or related field with at least 10 years of directly related experience in the pharmaceutical/biotech industry, or Master's Degree with at least 12 years of directly related experience.
- Experience working on all phases of clinical trials (Phase 3 international clinical trials is a plus).
- Thorough understanding of statistical principles and clinical trial methodology with the ability to practice and implement them
- Experience working on NDA/MAA development and submissions, including hands-on experience working on ISS/ISE.
- SAS programming expertise and familiarity with R and Python programming.
- Understanding of ICH GCP as well as knowledge of industry practices and standards.
- Demonstrated knowledge of regulatory guidelines relating to statistical analysis, study reports and statistical components of regulatory submissions
- Demonstrates organizational skills; able to prioritize workload
- Strong written and oral communication and presentation skills.
- Proficiency with Microsoft Office (Excel, Word, Outlook, PowerPoint, Project).
- Familiarity with CDISC/SDTM/ADaM data standard specifications.
- Project and vendor management experience is a plus.