Job Title – Associate Director/Director, Regulatory CMC

Location – Onsite San Diego

LENZ Therapeutics is a late-stage clinical company developing innovative ophthalmic pharmaceutical products that improve vision, proudly based in San Diego. LENZ employees are united in a mission to improve and sustain vision. We are passionate and creative about applying scientific innovation to meet the needs of the millions of people worldwide who suffer from Presbyopia and other ophthalmic maladies. We focus on the development and commercialization of new therapies to bring our mission to life for patients every day.

We are committed to providing an engaging, rewarding work experience that reflects the passion our employees bring to our mission to improve and sustain vision. Our company fosters a diverse and inclusive culture where our employees are encouraged to learn, grow, and innovate, while making a meaningful difference for millions of people around the world.

LENZ provides equal employment opportunities to all employees and applicants.

Overall Purpose: The AD/Director, Regulatory CMC supports the development and successful performance of the CMC regulatory strategy for LENZ Therapeutics. This position is based in San Diego, CA and reports to the VP, Regulatory and Clinical Operations.

Key Responsibilities of the Role:

- Create CMC regulatory strategy for original submissions and changes to approved processes.
- Interpret global CMC regulations and guidance to identify risks and provide input for guidance to cross functional product teams.
- Partner with cross-functional stakeholders to deliver input on regulatory submissions (e.g. CMC component(s) of IND / NDA / Master Files, amendments, supplements, annual reports and health authority interaction briefing documents).
- Manage regulatory dossiers throughout the product development lifecycle.
- Lead complex programs.
- Write and review submission documents to ensure that correspondence is of the highest quality in terms of content, organization, clarity, and accuracy.
- Represent CMC regulatory affairs on product teams and in health authority interactions.
- Provide regulatory assessments for manufacturing changes and quality compliance and participate in technical risk assessment exercises.
- Support the development and maintenance of regulatory templates, best practices, and procedures.

LENZ THERAPEUTICS

Qualification Requirements:

Expertise:

- Prior experience in drug/device combination products strongly preferred.
- In-depth knowledge of global CMC regulations and understanding of evolving challenges and health authority expectations.
- Experience in IND and NDA filings.

Education and Experience:

- MA/MS degree in life sciences required, advanced degree preferred (PhD, PharmD).
- Experience of 10+ years with BS/BA; 8+ years with MS/MA or MBA; 6+ years with PhD.

Physical Demands and Work Environment

Typically works in an office environment. May, on a continuous basis, sit at desk for a long period of time, intermittently answer telephone and write or use a keyboard to communicate through written means. Some walking and lifting up to 20 lbs. may be required. The noise level in the work environment is usually low to moderate. Must be flexible to work varying schedules and hours as needed. Frequent out-of-town travel will be required. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Salary Range

- $185-220k DOE