Job Title – Sr. Quality Specialist

Location – On-site Solana Beach

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.

Key Responsibilities of the Role:

- Data review and verification
    - Review and release of batch records and data for product release.
    - Review of regulatory submissions against source data for CMC, Clinical and non-Clinical sections of marketing applications.
    - Review external manufacturing, testing records and internal quality records to support investigations related to CAPAs, Quality Events, Product Quality Complaints, and Adverse Event Reports.
- Support Quality Management processes including Document Control, Quality Events, CAPA, Change Control, Internal Audit and Training.
    - Author Policies, Procedures, Work Instructions, and Forms.
    - Route GxP documents through the respective eQMS system.
    - Issue Training tasks, monitor completion and report on system status to Management.
    - Work with various groups to ensure training curriculums remain current for new staff and as new procedures are introduced.
    - Maintain design history files and related documents related to device constituents and finished combination products.
- Support the administration of electronic QMS and Regulatory software(s)
    - Add and remove permissions, as necessary, for LENZ staff.
    - Update workflows, metadata, and configurations as needed by users.
    - Oversee software lifecycle management to ensure changes made by vendor and LENZ are properly evaluated and documented through appropriate change management processes.

- Support Product Complaint Handling
    - Review batch release and stability data as part of investigations.
    - Evaluate historical trends .
    - Provide data on program compliance.

- Support Management Review program
    - Coordinate meetings, report on attendees and topics.
    - Trend, prepare, and present data on the various quality management systems.

Additional Dimensions:

- Support supplier management activities including:
    - Maintaining supplier audit schedule, approved supplier list and tracking completion of supplier audits and responses received.
    - Maintaining Supplier Quality Assurance Agreements.
    - Performing audits, as needed.
    - Interacting with suppliers as needed.
- Support Clinical Quality activities
    - Maintain schedule and documentation for Clinical site and TMF audits.
    - Participate in Clinical site and TMF audits, generate audit reports and track closure.
- Support Regulatory Submissions
    - Support the publishing of submissions as needed by the Regulatory group.
    - File communications with Regulatory Agencies in files, as needed.
    - Perform source data verification for promotional and labeling materials.

Qualification Requirements:

Expertise:

- Must be familiar with Quality Systems required for the management of drug-led combination products.

- Must be able to excel in a fast-paced pharmaceutical environment with a variety of responsibilities.

- Highly organized and able to prioritize multiple independent activities.

- Able to work independently to deliver on company and department goals and objectives.

Education and Experience:

- Bachelor's degree, physical/life sciences preferred.
- Minimum of 6-8 years in pharmaceutical, medical device or regulated industry.

- Minimum of 3-5 years in Quality related role(s).
- Experience working in small, fast-paced, entrepreneurial organizations preferred.
- Experience working in electronic systems with some administrative experience preferred.

Physical Demands and Work Environment
Typically works in an office environment and at ophthalmic practitioner's locations. 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
•$115,000-125,000