LENZ THERAPEUTICS

Job Title – Quality Specialist (Product Complaint)

Location – Solana Beach, CA

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:

Support the development, implementation, and maintenance of Quality Systems necessary for the commercial launch and maintenance of ophthalmic combination products. Position focus is supporting Product Complaint process for commercial product.

Key Responsibilities of the Role:

- Oversee and Maintain Product Complaint Handling
    - Assist in developing and establishing product quality complaint system.
    - Investigate and report on product quality complaints.
        - Escalate (as required) complaints that may indicate significant quality concerns with distributed product.
        - Review batch release and stability data as part of investigations.
    - Establish, Track, and Trend product quality complaint metrics.
        - Provide data on program compliance.
- Data review and verification
    - Review and release of batch records and data for product release.
    - Review external manufacturing, testing records, and internal quality records to support investigations related to CAPAs, Non-conformances, Product Quality Complaints, Adverse Event Reports
    - Review of regulatory submissions against source date for CMC, Clinical and non-Clinical sections of marketing applications.
- Support Quality Management processes including Document Control, CAPA, Quality Events, Change Control, Internal Audit and Training.
    - Author Policies, Procedures, Work Instructions, Forms

    - Route Quality Records through the respective workflows
    - 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 Management Review program
    - Schedules meetings, report on attendees and topics
    - Work with senior quality management to establish Quality Metrics for the tracking and reporting of key performance indicators (KPIs) and quality metrics to monitor the effectiveness of quality systems and processes.
        - Trend, prepare, and present data on the various quality management systems.

Additional aspects for the Role:

- Manage/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 supplier management activities including:
    - maintaining supplier audit schedule, approved supplier list and tracking completion of supplier audits and responses received.
    - Tracking Supplier Quality Agreements
    - Performing audits, as needed.
    - Interacting with suppliers
- 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.
- Must have prior experience with Product Quality Complaint Systems and electronic QMS systems.
- 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 years in pharmaceutical, medical device or regulated industry
    - Quality Specialist – Minimum of 1-6 years
    - Sr. Quality Specialist – Minimum of 6+ years.
- Minimum years in Quality related role(s).
    - Quality Specialist – Minimum of 1-3 years.
    - Sr. Quality Specialist – Minimum of 3+ years.
- Experience working in small, fast-paced, entrepreneurial organizations preferred.
- Experience working in electronic systems with some administrative experience preferred.

Travel

- 5-10% travel possible; domestic and international

Physical Demands and Work Environment

Position is based in-office. 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. Occasional out-of-town travel may 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

- Quality Specialist – $70,000-$105,000
- Sr. Quality Specialist – $110,000-125,000

Mission Statement:

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