LENZ THERAPEUTICS

Job Title – Associate Director, Quality Assurance

Location – San Diego with travel

Overall Purpose: Lead the development, implementation, and maintenance of Quality Systems necessary for the commercial launch and maintenance of ophthalmic combination products.

Key Responsibilities of the role:

- Responsible for the implementation and maintenance of Quality Systems including Document Control, Training, CAPA, Change Control, Design Control, Internal Audit and Training:
  - Author/Review Policies, Procedures, Work Instructions, Forms
  - Oversee the processing of 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.
  - Responsible for scheduling and content of Management Review meetings.
- Oversee Supplier Management activities including:
  - Ensuring supplier audit schedule and approved supplier list is maintained including the completion of supplier audits and responses received.
  - Developing and approving Supplier Quality Agreements
  - Performing audits, as needed.
  - Working with suppliers to foster strong relationships and partnerships to support development and commercial success.
- Oversee Risk Management program:
  - Ensuring risk management is effectively and efficiently implemented throughout the Quality Systems.
- Maintain systems and processes that ensure effective product release and data integrity programs:
  - Release batch records and data for commercial product release.
  - Ensure Quality reviews of regulatory submissions against source data for CMC, Clinical and non-Clinical sections of marketing applications.
  - Ensure external manufacturing and testing records and internal quality records are effectively reviewed to support investigations related to CAPAs, Non-conformances, Product Quality Complaints, Adverse Event Reports.
- Responsible for the GxP software compliance is maintained in a state of compliance:
  - Ensure systems are validated and maintained in a validated state

through changes to workflows and software.
    - Ensure software lifecycle management effectively evaluates changes made by vendor and LENZ are properly evaluated and documented through appropriate change management processes.
    - Develop appropriate KPIs and trending to evaluate the performance of the Quality systems.
- Develop a strong Quality team:
    - Build and efficient and versatile Quality team able to transition between various roles and responsibilities.
    - Develop the quality team through leadership and mentoring which operates in support and partnership with other internal LENZ functions.
- Act as back up to VP, Quality as needed.

Additional Dimensions:

- Support Clinical Quality activities:
    - Maintain schedule for Clinical site and TMF audits.
    - Participate in Clinical site and TMF audits, generate audit reports, 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 experienced with all areas of Quality Systems required for the management of drug-led combination products.
- Must have the experience and ability to interpret and move between Drug and Device regulations and guidance for compliance decisions.
- Must be able to excel in a fast-paced pharmaceutical/combination 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.
- Must be able to lead staff and operate as an individual contributor as circumstances dictate.
- Ability to travel up to an average of 10-20% (international and domestic travel).
- Strong computer skills including Microsoft Excel, Word, PowerPoint, SharePoint, Teams, and knowledge of ERP/MRP systems.

Education and Experience:

- Bachelor's degree, physical/life sciences preferred.
- Minimum of 10-15 years in pharmaceutical, medical device or regulated industry.

- Minimum of 8-10 years in Quality related role(s).
- Minimum of 6 years' experience in management roles.
- Experience working in small, fast-paced, entrepreneurial organizations preferred.
- Experience working in electronic systems with some administrative experience preferred.
- Experienced in both Pharmaceutical and Device.

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 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
- $165,000 - $180,000

Mission Statement:
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.