Job Title – Process Engineer

Location – 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:

We are seeking an experienced and driven Process Engineer to join our dynamic team at LENZ as we prepare to commercialize our lead asset LNZ100. Reporting directly to the Director of External Manufacturing, this pivotal role requires a strategic thinker with experience manufacturing pharmaceutical products, managing CMO's, API suppliers and analytical laboratories, as well as multi-arm stability programs. The ideal candidate will also have experience with Blow-Fill-Seal (BFS) manufacturing, supporting CMC regulatory submissions, managing statistical analysis tools for trending stability data, and providing experienced technical support of GMP operations at CMO's as Person-In-Plant all while working in a high-paced environment to deliver innovative therapies to patients in need.

Key Responsibilities of the Role:

- Provide technical support of GMP operators at CMO's as Person-In-Plant (PIP).
- Main technical point of contact between LENZ and external manufacturing and analytical partners. Responsible for overseeing manufacturing and analytical testing activities including API production, Drug Product formulation and filling, release testing, and stability program oversight.
- Support cross-functional teams in troubleshooting and resolving manufacturing related issues, problem solving, CMC risk assessments, and development of improvement plans.
- Provide NDA and regulatory filing support for CMC related sections including Drug Substance, Drug Product, Analytical, and Stability data.
- Apply statistical methods to various production performance datasets to monitor, track and trend, and/or assess opportunities for improvement in capacity, yield, and/or utilization, as well as KPI reporting.
- Collaborate with external partners to troubleshoot and investigate issues that

arise within the manufacturing process and effectively communicate findings in a timely manner.
- Coordinates with CMOs on product process design changes and process improvements to manage product life cycle and CMC risk management.
- Support Drug Product batch record review and disposition activities with LENZ's Quality Assurance team.
- Technical support for technology transfer and process/equipment scale-up activities with primary and secondary/tertiary suppliers.
- Supports analytical method transfers and validation to secondary/tertiary contract laboratories.
- Coordinates manufacturing and testing schedules with CMOs for clinical, registration, process validation, and commercial batch execution.
- Write and review technical documentation (batch records, SOPs, protocols & reports).
- Perform data analysis based on clinical MFG process and commercial product data.
- Additional duties as assigned.

Additional aspects for the Role:

- Foster a culture of continuous improvement and operational excellence.
- Ensure clear communication and collaboration across all levels of the organization.
- Partners proactively with key customers, team members, external vendors, and stakeholders, while being open and approachable with a friendly, positive and professional attitude.
- Enjoy working in a high-paced environment, able to manage competing priorities effectively and adapt to changing priorities.
- Ability and willingness to travel both domestically and internationally 40-50%.

Qualification Requirements:

Expertise

- Strong background in cGMPs, Manufacturing, Analytical, Process Engineering, and/or CMC roles.
- Experience working at/with a CMO in Drug Substance and/or Drug Product manufacturing roles.
- Blow-Fill-Seal (BFS) manufacturing experience preferred.
- Experience working with analytical Labs and vendors for both clinical and commercial drug products.
- Strong understanding of cGMP, 21CFR part 210 & 211, and other regulatory aspects of aseptic compounding and sterile Blow-Fill-Seal manufacturing.
- Project Management skills and experience; including strong collaboration, organization, communication skills, and results focused.
- Demonstrated ability to multi-task and execute work in a timely manner within a fast-paced environment.

- Ability to drive multiple initiatives at one time in a fast-moving environment where the expectations to always deliver results will be high.
- Strong team player and a demonstrated track record of playing a key role in a business environment.
- Strong communicator that has shown to be able to both verbally and in written word adapt to the style of communication appropriate to their intended audience.
- Strong computer skills including Microsoft Excel, Word, PowerPoint and knowledge of ERP/MRP systems.

Education and Experience:

- BS or BA in Chemistry, Biology, Chemical Engineering, Engineering, or similar.
- 5-7 years of biopharmaceutical experience.

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

- $ 125,000-135,000

Mission Statement:

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