LENZ THERAPEUTICS

Job Title – Sr. Regulatory Operations Specialist

Location – Onsite, 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.

Overall Purpose:

We are seeking a detail-oriented and highly organized Senior Regulatory Operations Specialist to join our Regulatory Affairs/Operations team. The Senior Regulatory Operations Specialist will be responsible for formatting and publishing regulatory submissions, supporting the implementation and maintenance of our Regulatory Information Management and publishing systems, and ensuring compliance with regulatory submissions requirements throughout the product lifecycle.

Key Responsibilities of the Role:

- **Regulatory Submissions Publishing:**
  - Format MS Word documents using software template tools
  - Compile, publish, and submit regulatory documents in eCTD format to health authorities, including FDA, EMA, and other global regulatory agencies.
  - Ensure the completeness, accuracy, and timeliness of regulatory submissions in accordance with regulatory guidelines and internal standards.
  - Maintain submission tracking systems to monitor submission status and timelines, proactively identifying and addressing potential issues or delays.
- **Regulatory Information Management System (RIMS):**
  - Maintain RIM System, ensuring data integrity, version control, and access permissions.
  - Support system configuration, user training, and troubleshooting to optimize functionality and usability for Regulatory Affairs/Operations and cross-functional teams.

- **Quality Assurance and Compliance:**
    - Perform quality control checks on regulatory documents and submissions to ensure compliance with regulatory requirements, company standards (style guide), and submission specifications.
    - Implement and maintain standard operating procedures (SOPs) for regulatory operations processes, ensuring alignment with regulatory guidelines and industry best practices.
- **Regulatory Intelligence:**
    - Monitor regulatory developments, guidelines, and requirements relevant to regulatory operations and submission activities.
    - Provide regulatory intelligence updates to internal stakeholders and support the interpretation and implementation of regulatory changes.
- **Cross-Functional Collaboration:**
    - Collaborate closely with Regulatory Affairs/Operations, Clinical Operations, Quality Assurance, CMC, and other functional areas to facilitate document collection, review, and approval for regulatory submissions.
    - Serve as a subject matter expert on regulatory operations processes and requirements, providing guidance and support to internal teams as needed.
- **Process Improvement:**
    - Identify opportunities for process optimization and efficiency improvements in regulatory operations workflows.
    - Recommend and implement enhancements to systems, tools, and procedures to streamline regulatory submission activities and enhance productivity.

Qualification Requirements:

Expertise

- Strong understanding of global regulatory eCTD requirements and guidelines governing the submission of investigational product and marketing applications (e.g., FDA, EMA, ICH).
- Proficiency in electronic document management systems and regulatory publishing tools (i.e., LORENZ, EXTEDO, Veeva).
- Excellent organizational skills, attention to detail, and ability to manage multiple priorities in a fast-paced environment.
- Effective communication and interpersonal skills with the ability to collaborate across functional teams.

Education and Experience:

- Bachelor's degree in a scientific discipline, regulatory affairs, or related field.
- Minimum of 3 years of experience in regulatory operations, regulatory affairs, or a related role within the biopharmaceutical or pharmaceutical industry.

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

- $115 – 135k DOE

Mission Statement:

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