

Job Title – Director, Legal Affairs and Compliance

Location – On-site, San Diego

LENZ Therapeutics is a pre-commercial 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.

Position Overview:

Reporting to the Chief Financial Officer, the Director, Legal Affairs and Compliance is responsible for the establishment, management and daily administration of an effective corporate compliance program. In addition, this position will serve as an in-house legal resource for standard corporate activities, contracting and other general purposes. This will be an on-site position Monday-Thursday, with remote location flexibility on Friday.

Key Responsibilities of the Role:

- Develop and implement a comprehensive compliance program to ensure the Company complies with all relevant laws and regulations.
- Create and adopt a Healthcare Compliance Audit and Monitoring Program to ensure compliance with the Sales and Marketing code of conduct that will require routine training of all sales and marketing staff, including corporate functions.
- Support the legal/compliance review on the MLR design and team.
- Manage and oversee the Sales and Marketing and Medical Affairs compliance programs (PhRMA Code, HIPAA, etc) and work with Training ensuring education and compliance by field organization
- Provide legal review of LENZ Therapeutics agreements including, but not limited to, master service agreements, quality agreements, consulting



agreements, clinical trial agreements, commercial, supply, and vendor agreements, as well as oversee the contract execution lifecycle (negotiate, execute, monitor, manage) within our contract management system (Ennov).

- Direct the development and implementation of compliance policies, procedures, guidelines and a Code of Conduct to facilitate compliance with federal, state and local laws, regulations and rules and industry standards.
- Collaborate with finance and sales teams to prepare and submit accurate Sunshine Act reports to the Center for Medicare and Medicaid Services within mandated deadlines.
- Maintain proficiency of laws and regulations for transparency compliance and disclosure requirements, including at the federal, state and local level, and specific international regions.
- Coordinate the development and implementation of compliance training for applicable employee groups.
- Set the strategic direction for compliance activities through annual risk assessments and work plans.
- Implement and execute training of ensure all LENZ Therapeutics employees, contractors and partners understand federal health care program requirements applicable to their specific roles and functions.
- Establishment of lines of communication / hotline to facilitate the reporting of compliance issues.
- Ensure appropriate investigations are conducted for alleged Code of Conduct and compliance policy violations and recommend corrective action.
- Conduct periodic internal reviews/audits of key business areas, systems, processes, and procedures to ensure that compliance with legal and policy requirements applicable to their operations.
- Assist in reviewing and approving various internal and external certifications and reporting of compliance and transparency disclosure requirements as required by business practice, regulation and/or law.
- Provide regular updates to the Executive Team.
- Maintain proficiency on current legal and compliance issues relating to the pharmaceutical industry and contracts for the same and perform tasks and other duties as required for effective implementation, management, and upkeep of contracts and agreements.
- Preparing formal and informal responses to governmental investigations, inquiries, and requests with guidance from Senior Management as appropriate



- Promoting compliance awareness throughout LENZ Therapeutics through training and other initiatives.
- Oversee a comprehensive approach to establishing a culture of accountability and compliance.

Qualification Requirements:

Expertise

- Possess knowledge and understanding of the compliance, legal and regulatory framework and industry standards affecting the pharmaceutical industry, including but not limited to Office of Inspector General (OIG), PhRMA Code, PDMA, AMA, and industry guidance documents, regulations regarding the promotion of marketed products, clinical trial regulations, and issues arising under the False Claims Act and anti-kickback statutes.
- Adept at reading and interpreting legal documents and regulations using proven critical thinking skills, decision-making, and program risk assessment
- Track record for successfully working cross-functionally on a wide range of pharmaceutical compliance activities
- High level of ethical standards and proven track record in gaining and maintaining trust and credibility with internal and external constituents
- Strong project management, conflict resolution and group facilitation skills
- Effective public speaking skills and an ability to communicate in both verbal and written form with a broad cross-section of management and employees throughout the company
- Strong analytical skills and demonstrated ability to exercise independent judgment and initiative
- Excellent interpersonal and communications skills
- Organization and planning resourcefulness
- Understanding of business needs
- Ability to analyze data, develops and maintains databases, and generate formal written reports
- Ability to influence others across the organization and working with third parties to lead and/or support continuous improvement programs to contribute to the maintenance of a strong compliance profile
- Demonstrated ability to create and manage work plans and timelines

Education and Experience:

- A B.A. or B.S. from a 4 year college or university of recognized standing is



required. A J.D. from a law school of recognized standing and state bar admission or other relevant graduate degree is a plus.

- Significant relevant experience in health care compliance and/or related fields is required.
- Knowledge of applicable laws, regulations and industry standards
- 10+ years of combined experience in legal and pharmaceutical compliance

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

- \$225k-\$250k DOE.

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.