n-lorem FOUNDATION

Position Title: **Regulatory and Development Operations Manager**
Reporting to: Executive Director, ASO Discovery and Development
Hours: Full-Time
Location: Decentralized
Compensation: $70K - $110K /annual.+ benefits

n-Lorem Foundation

n-Lorem is a non-profit foundation founded in 2020 committed to discovering, developing and providing experimental treatments to patients who have genetic diseases caused by nano-rare mutations that affect 1- 30 patients worldwide - for free for life. We leverage decades of experience in antisense oligonucleotide (ASO) technology and a roadmap described in 4 FDA guidance documents from 2021. Since establishment over 4 years ago, n-Lorem has grown to meet the needs of the nano-rare patient community and have successfully filed >10 INDs for n-Lorem ASOs with plans to submit many more as the programs advance. We continue to be in an exciting time of significant growth while we establish and scale our infrastructure- and know that this endeavor is only possible with a strong team.

Job Overview:

The Regulatory and Development Operations Manager will be responsible for the operational aspects of all regulatory activities, in addition to supporting the preclinical and clinical development teams with the development, authoring, editing, reviewing or processing of various documents directly or indirectly related to regulatory submissions. We are seeking an experienced individual with attention to detail, who is quick and eager to learn, goal-oriented, and self-motivated. The successful candidate will work closely with the preclinical and clinical development team to implement efficiencies in regulatory operations across the board. It is of the utmost importance to be able to work in a fast-paced biotech-like environment.

Job Duties:

- In collaboration with cross functional teams, develop timelines for submissions to regulatory authorities
- Support cross functional teams in the authoring of high-quality regulatory communications such as regulatory meeting requests, briefing packages, responses to regulatory health authority requests, and IND components
- Support preparations for, and participate in, meetings with regulatory agencies to ensure efficient drug development, product license approvals and their maintenance
- Act as the main point of contact for interactions with regulatory authorities
- Track upcoming regulatory milestones (initial submissions, hold and non-hold responses, annual reports)
- Track and maintain on file all regulatory documentation

- Gather input from key stakeholders to efficiently respond to inquiries from regulatory agencies in a timely manner
- Proactively map out regulatory pathways in territories outside the US, and develop roadmap, timelines, templates and any other tools to support the development team in getting submission-ready in new territories
- Provide crisp review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, consistency and clarity of presentation
- Develop, maintain and improve templates for various documents including nonclinical or clinical protocols, cover letters, pharmacy manuals, IND sections or others
- Prepare and revise internal regulatory procedures for continuous improvement
- Other duties as assigned to contribute to the development of the infrastructure needed to support an ever-growing portfolio of programs at various stages

Requirements

- US work authorization
- BSc, MS or PhD degree in a scientific discipline required
- Minimum of 3 years of experience working in the pharmaceutical/biotechnology industry
- Familiarity with the interpretation of applicable FDA guidances
- Demonstrated experience in preparation and submissions of INDs and/or other regulatory applications is a plus
- Familiarity with Canadian, EU, UK and ICH guidelines related to clinical trial and marketing applications is a plus
- Proven ability to effectively work collaboratively in cross-functional teams and lead team discussions and handle competing priorities.
- Flexibility within a rapidly changing environment and high attention to details.
- Highly organized and able to project manage the regulatory components of an ASO program to meet agreed upon milestones and the ability to thrive under pressure
- Energetic, self-motivated and a hands-on professional with a strong work ethic
- Intermediate to advanced software skills (e.g., Office 365, Microsoft Excel, PowerPoint).

References

- Initial FDA guidance for ASO for patients with diseases caused by ultra-ultra-rare mutations: Jan. 4, 2021
- Pre-clinical requirements: Detailed guidance April 2021
- CMC guidance Dec 2021
- Clinical guidance Dec 2021

n-Lorem offers a competitive benefits package including medical, dental, vision, 403(b) retirement plan with a match and 4 weeks paid vacation. n-Lorem is a small foundation with an extraordinary mission, to provide hope and potentially help to nano-rare patients today. Every employee in our organization is a significant contributor to this mission. We know that our work could have a profound impact on the life of a patient today.

For more information on n-Lorem, please visit our website www.nlorem.org

COVID-19 update:

We are pleased that 100% of n-Lorem employees/temps who have reported their vaccination status are vaccinated against the COVID-19 virus.

Additional COVID-19 precautions

All employees, and contractors/consultants regularly working on-site are strongly encouraged to be fully vaccinated against the COVID-19 virus.