Title: (Senior) Manager, Regulatory Affairs

Line Manager: Associate Director, Regulatory Affairs

Location: Paris, FR

Employment type: Full-time

Our Company

SparingVision is a clinical stage genomic medicines company with a mission to translate pioneering science into vision saving treatments. Leveraging its unparalleled understanding of retinal diseases, SparingVision has built the world's most compelling portfolio of synergistic cutting-edge gene therapy and genome editing treatments for inherited retinal diseases (IRDs). Both of its most advanced products, SPVN06 and SPVN20 look to go beyond single gene correction therapies to deliver new mutation agnostic treatments for Retinitis Pigmentosa (RP), a group of IRDs which are the leading cause of blindness globally. The Company also has a strategic collaboration with Intellia Therapeutics (NASDAQ: NTLA) to develop novel genome editing-based treatments for ocular diseases utilizing CRISPR-Cas9 technology.

SparingVision was spun out from the Paris Vision Institute in 2016. With 135M€ in Series A (2020) and Series B (2022) funding, it is backed by high-quality international investors including 4BIO Capital, AdBio Partners, Bpifrance, Fondation Voir & Entendre, Intellia Therapeutics, Jeito Capital, RD Fund (US), UPMC Enterprises, and Ysios Capital.

For more information on the company, please visit the website at:
https://sparingvision.com

Job summary

SparingVision seeks a Manager/Senior Manager, Regulatory Affairs to contribute to the overall success of the company working to develop cures for ophthalmic diseases using novel gene therapy approaches.

The candidate must be able to interpret international biologic/ATMP regulations as they apply to given phases of drug development including preclinical, clinical and commercial. This is an exciting hands-on role within SparingVision where the individual will play a key role in a growing regulatory team. The position is based in the Paris, France headquarters and the successful candidate will be reporting to the Associate Director, Regulatory Affairs.

Main Responsibilities

- Coordinate the preparation, submission, management and maintenance of high-quality INDs and CTAs in the US, EU and UK mainly for SparingVision's interventional and non-interventional clinical studies according to set timelines; this requires close interactions with the SparingVision Clinical Operations team members and the various sub-contractors
- Support in the development and implementation of global regulatory strategies for SparingVision's gene therapy pipeline, including early-stage assets, in accordance with global regulations and guidance
- Support in the submission of high-quality regulatory dossiers in the US, EU and UK mainly, according to set timelines; this includes (but is not limited to) PRIME, RMAT, Scientific Advice, PIPs and BLA/MAA, and requires strong regulatory knowledge and experience, cross-functional interactions, excellent project management and writing skills, and a deep understanding of the underlying science
- Upon delegation, serve as Competent Authority and Ethics Committee liaison and drive certain aspects of interactions and negotiations toward anticipating, clarifying and solidifying SparingVision's development/commercialization strategy
- Contribute to the maintenance of up-to-date global regulatory intelligence and competitor trends/strategy, analysis and dissemination within SparingVision
- Contribute to the development and maintenance of dedicated regulatory SOPs and associated quality documentations within SparingVision's Quality Management System

Qualifications

- Pharmacist or Master's degree in applicable life sciences field
- 3+ years of experience serving in a regulatory science position, preferably in a biotech environment
- Good knowledge and skill base experience with the development of therapeutic ATMPs
- Strong knowledge of GxP/ICH/FDA/EU regulations and guidances
- Excellent communication and organizational skills, sufficient to multi-task in an extremely fast-paced environment with changing priorities

- demonstrated ability to work in a productive and collaborative cross-functional manner
- This position may require some (05%-10%) international and domestic travel

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions and perform any other related assigned duties.

SparingVision is an Affirmative Action and Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, age, national origin, or protected veteran status and will not be discriminated against on the basis of disability.