Title: Director/VP, Regulatory Affairs

Line Manager: COO

Location: Philadelphia, PA or Cambridge, MA **Employment type: Full-time**

Our Company

SparingVision is a genomic medicines company, translating pioneering science into vision-saving treatments. The Company is supported by a strong, internationally renowned team who aims to harness the potential of genomic medicine to deliver new treatments to all ocular disease patients as quickly as possible. SparingVision has raised €60 million to date and recently signed a deal with Intellia Therapeutics to use Intellia editing technology in eye diseases. The company was founded in 2016 and employs 25 people in France and in the US and has an ambitious growth plan over the next two years.

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

Job summary

The Dir./VP, Regulatory Affairs will drive the strategy and execution of SparingVision regulatory affairs through management and structuration of his/her team according to projects expansion and ownership of the alignment of the regulatory strategy in accordance with project stage of development. The Dir./VP, Regulatory Affairs will establish and improve regulatory affairs processes and tools.

Responsibilities

- Governance and oversight of SparingVision regulatory activities
  - Establish, continuously monitor, and improve regulatory processes and tools
  - Establish a close reporting with upper management
- Regulatory roadmap and execution
  - Design and development of regulatory roadmap in alignment with SparingVision corporate strategic plans.
  - Lead strategic planning, anticipate changes, and manage risk (identify pivot point and constraints)

  - Drive and oversight execution of regulatory document preparation and submission to US, EU and JP agencies
  - Ensure compliance of SparingVision to FDA and EMA standards
- Resource Management
  - Manage, coordinate, allocate resources in accordance with needs
  - Partner with CMO, CTO, CDSO and COO to facilitate global coordination of the regulatory strategic plan
  - Establish and continuously monitor budget for regulatory activities. Liaise with VP, Portfolio Project Management for alignment

Accountabilities

- Delivery of strategic regulatory roadmap
- Management and development of the team

Leadership & Stakeholder management

- Build and maintain strong working relationships within SparingVision.
- Build and lead a group that is responsible for entire regulatory strategy.
- Provide direction to staff
- Select, develop, and motivate staff to effectively carry out department function
- Coach and mentor staff in all aspect of their job performance

Qualifications

- Engineering degree or equivalent, PharmD, PhD in life science
- At least 15-year experience in pharmaceutical development in the biotech/pharma industry, where you were strategic & operational to prepare IND/IMPD/BLA/MAA.
- Fluency in French and English, both written and oral
- Action planner, ability to challenge, ability to meet and enforce deadlines
- Strength of proposal, ability to develop scenarios,
- Team oriented and ability to lead and make a team grow,
- Computer skills including proficiency in MS Offices softs,
- Ability to review processes and identify the critical elements,
- Competitive, able to demonstrate leadership skills and highly motivated.

Candidates must be authorized to work in the U.S.

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.