SPARINGVISION

VP, Regulatory Affairs and Quality Assurance

Title: VP, Regulatory Affairs and Quality Assurance
Line Manager: COO
Department: Operations
Location: Paris, France

JOB SUMMARY

The VP, Regulatory Affairs and Quality Assurance will drive the strategy and execution of SparingVision regulatory affairs and quality assurance through management and structuration of his/her team according to projects expansion, ownership of the alignment of (1) the regulatory strategy in accordance with project stage of development and (2) the quality environment to meet clinical and CMC standard. The VP, Regulatory Affairs and Quality Assurance will establish and improve RA & QA processes and tools.

ESSENTIAL FUNCTIONS

- Governance and oversight of SparingVision regulatory and quality activities
  - Establish, continuously monitor, and improve regulatory and quality processes and tools
  - Establish a close reporting with upper management
- Regulatory and Quality roadmap and execution
  - Design and development of regulatory and quality 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
  - Drive and oversight execution of the quality system set up, development and continuous improvement for clinical and CMC
  - Ensure compliance of SparingVision to FDA and EMA standards
- Resource Management

- Manage, coordinate, allocate resources in accordance with needs
- Partner with CMO, CTO and COO to facilitate global coordination of the regulatory strategic plan and set up of clinical and CMC quality
- Establish and continuously monitor budget for regulatory and quality activities. Liaise with VP, Portfolio Project Management for alignment

ACCOUNTABILITIES

- Delivery of strategic regulatory and quality 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 and quality 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

PROFILE

- Engineering degree or equivalent, PharmD, PhD in life science
- At least 10-year experience in pharmaceutical development in the biotech/pharma industry, where you were strategic & operational to prepare IND/IMPD and where you participate/lead quality assurance system set up.
- 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.

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.

The position is based at SparingVision Headquarters in Paris, France. The VP, Regulatory Affairs and Quality Assurance will report to the COO.