REGULATORY AFFAIRS MANAGER

Contract: CDI, permanent, based in Paris, 74 rue du Faubourg St Antoine

BrainEver is a young biopharmaceutical company aiming at developing highly innovative therapies for the treatment of neurodegenerative diseases (http://brainever.com/). Two projects are currently in preclinical phase, one for the treatment of Parkinson Disease, and the second for the treatment of Amyotrophic Lateral Sclerosis.

We are looking for a Regulatory Affairs Manager to join our development team to ensure smart and effective drug development of BrainEver's products. This position requires a strong scientific and regulatory expertise, advanced leadership skills and ability to effectively collaborate with colleagues and external partners.

Responsibilities / Activities

The Regulatory Affairs Manager will be responsible of the following operations:

- Proactive member of the Project Team representing Regulatory Affairs perspective for all activities (CMC, preclinical, clinical)
- Build the regulatory development strategy in collaboration with the project team to ensure successful drug development,
- Ensure that all activities are conducted in compliance with current regulations, laws and guidance from regulatory bodies and ICH/GCP guidelines
- Lead all regulatory activities and relationships with Competent Authorities and Ethics Committees: set-up and monitoring of regulatory plan, preparation and submission of CTA/IND package, preparation and coordination of Scientific Advices / preIND dossier, submission of periodic pharmacovigilance reports to Health Authorities
- Maintain and develop regulatory expertise by continuous regulatory surveillance, competitive intelligence and keeping up to date a network of external experts
- Manage external regulatory subcontractors: request for proposal; CRO selection and management; ensure high quality deliverables/output
- Set-up and follow-up of the Data Protection Act implementation, in collaboration with Brainever's legal director,
- Work closely with Brainever's Project Leader for scheduling project regulatory activities

Qualifications, experience and skills

- Scientific background with at least 10 years' experience in regulatory affairs with a strong focus on biologics development (ie. recombinant protein) and expertise in:
  - ✓ Early development CTA/IND submissions
  - ✓ Chemical, Manufacturing and Controls (CMC) dossier writing
  - ✓ Scientific Advice and preIND meetings
- Experience with complex and innovative therapies (drug or administration route) is appreciated
- Strong knowledge and understanding of European and International (ICH, US CFR) Regulatory Guidelines
- English fluent (oral and written)
- Strong verbal and written communication skills
- Entrepreneurial spirit, sense of urgency
- Rigorous, output and quality-oriented mindset
- Autonomous and good organizational skills
- Team player – works in close collaboration with all the departments: clinical, CMC, pharmacology, preclinical…