EG 427

PINPOINT GENE THERAPY

Job description

EG 427, a French biotechnology company that pioneers a new approach in gene therapy called pinpoint gene therapy, is looking for its:

Director of Clinical Operations

Full time position

Paris, France

Open to frequent travels (20% - including international travels)

Overview

EG427 is developing innovative treatments for patients suffering from conditions with unmet medical needs. The Director, Clinical Operations will be responsible for the operational conduct of the clinical studies and oversight of the Contract Research organizations involved. The position will also develop and structure the expertise in house and internalize new processes/methods/tools.

Based in the Paris office, the Director, Clinical Operations reports to the COO.

Mission

- Oversight of the clinical Contract Research organizations in all operational aspects with focus on study start -up, site management, clinical monitoring, and study close out.
- Close collaboration with the Chief Medical Officer/ Clinical Development for the clinical operational aspects of the clinical studies.
- Input into the selection of the Contract Research organizations, vendor selection, and budget negotiations with all functions involved.
- Collaboration on budget projections with Project management and Clinical Development.
- Responsible for enrollment projections for the clinical studies.
- Input into the site selection process in collaboration with the Chief Medical Officer/ Clinical Development.
- Oversight of the Informed consent process and content in collaboration with the Chief Medical Officer/Clinical Development, responsible for the internal review and approval of the Master Informed consent.
- Collaboration with the investigative sites on operational aspects of the clinical studies.
- Review of the clinical monitoring reports.
- Identification and proposed risk mitigation regarding enrollment challenges or other clinical operational aspects.
- Oversight of the data entry and cleaning process at the Contract Research organization, data reviews and data base lock in collaboration with the Chief Medical Officer/ Clinical Development and the respective data manager and statistician.

- Presentations at Investigator meetings or to Senior Management.
- Management updates on the clinical operational aspects of the clinical studies as regular dashboards or presentations as required.
- Collaboration with QA with respect to study site audits or the audit of a clinical vendor.
- In collaboration development of Clinical Operations SOPs, as required.
- Any other duties the company may assign.

Skills

Education: at least Master of Science or equivalent in a biological-science field or Physician Assistant or Nursing degree or Pharmacist.

Languages: native language and fluent in English (spoken and written).

Professional experience & know how: at least 5 years of experience in international clinical operations in drug development in a multi-disciplinary team, including collaboration with the US. Experience in working with CROs/ contract research organizations. Previous experience at a Sponsor company (pharmaceutical industry, biotech) would be an advantage. Previous experience in gene therapy development would be a plus. Profound knowledge of ICH – GCP.

Personal & interpersonal skills: Strong organizational and collaboration skills. Strong executional skills (ability to meet deadlines). Strong communication and leadership skills. Independent, flexible, pro-active, self-motivated and passionate about Clinical Operations. Ability to work in a biotech environment and rapidly changing environment. Ability to work in a cross-cultural environment.

We're looking forward to receiving your application!

- Cover letter
- Resume
- Contact details of three referees
- Miscellaneous documents (if any) to support your application

Please send your application to info@eg427.com
EG427 is an equal opportunity employer and values diversity within our company. We do not discriminate in any way. We make hiring decisions based solely on your experience and skills.