



Director of Clinical Operations

Company Information:

Stealth Peptides Inc. is a private-invested company dedicating in the discovery, development and commercialization of novel mitochondria targeting peptide therapeutics that address significant unmet medical needs. MTP-131 is the first-in-class molecules to target and directly protect mitochondria. It is Company's the lead compound for the Phase I and Proof of Concept studies in human subjects. Company's headquarter is located in Maryland with subsidiary R&D operation in Shanghai, China. This position is available immediately.

Position Responsibility:

- Selection and coordination of clinical CROs, Data Management/Safety Monitoring companies and clinical investigational sites.
- Communication and coordination with Medical Advisory Committee members.
- Assistance the development of clinical documents, such as investigational plans, investigator's brochure and clinical study protocols.
- Selection and management of Contract Research Organizations and investigative sites.
- Safety monitoring and reporting per FDA guidance.
- GCP compliance in clinical trials.
- Analysis of data from clinical trials; preparation of IND annual reports and clinical study reports as indicated.
- Preparation of study budgets and controls of costs.

Preferred Qualifications:

- Minimum of 5 years in pharmaceutical industry and 2 years management experience in clinical project management and operation, preferably in renal and cardiovascular products.
- Extensive knowledge about FDA/EMEA regulations on clinical studies and GCP compliance.
- Deep experience in all aspects of managing teams conducting Phase I-III clinical trials, including multinational studies is required.
- Direct experience in the management of CROs and other clinical research service providers.
- PhD, RN/RPh or MS in scientific discipline.

Please send your CV, qualification and contact information directly to:
info@stealthpeptides.com