CLINICAL RESEARCH ASSOCIATE (M/F)

Cellaïon SA is a global innovator in liver therapeutics whose mission is to bring life-saving treatments to reduce the need for liver transplantation. Our lead clinical program, derived from our patented cell technology platform HepaStem®, is designed to benefit from its immune-modulatory and anti-fibrotic properties.

Cellaïon SA is currently hiring a **Clinical Research Associate (CRA).**

As a Clinical Research Associate in our company, you will have administration and full investigator site responsibility for clinical studies according to Cellaïon Standard Operating Procedures (SOPs), ICH-GCP and applicable regulations.

You will ensure clinical trials are monitored such that subjects' rights, safety and well-being are protected and that the clinical trial data are reliable.

YOUR RESPONSIBILITIES:

- Develop protocols, informed consent forms, CRFs and CRF instructions, site selection materials, training materials, regulatory binders, study coordinator handbooks, other monitoring tools as required by the study, as well as study specific guidelines.
- Involved in recruitment of potential Investigators, preparation of Independent Ethics Committee/ Independent Regulatory Board (IEC/IRB) submissions, notifications to regulatory authorities, translation of study related documentation, organization of meetings and other tasks as instructed by the CSM.
- Negotiate investigator budgets and assist with the execution of site contracts with support from the legal department.
- Establish, update, track and maintain study specific trial management tools/systems, and status reports.
- Conduct site initiation visits with study site staff for the purpose of training about or reviewing of: drug accountability, SAE reporting, protocol, study procedures, document retention requirements, patient recruitment and retention requirements, GCP and regulatory requirements. Outstanding regulatory documents are also collected during such visits.
- Develop patient enrollment strategies with the project team and clinical trial sites.
- Conduct monitoring visits: ensure adherence to protocol, trial oversight, accurate data collection via comprehensive source document verification, and investigational product/biological samples/supplies accountability; ensure the integrity of clinical data with respect to accuracy, accountability, documentation and methods or procedure through review of case report forms (CFRs), source documents and medical records.
- Communicate effectively with site personnel, including the Principal Investigator (PI), and Cellaïon to relay protocol/study deviations and ensure timely implementation of corrective and preventive actions.

- Ensure proper storage, dispensation and accountability of clinical trial materials.
- Conduct study site close out visits for the purpose of inventory and return of all study drug, collect remaining CRFs and a final study report, resolve remaining data clarification and final subject status and ensure compliance with regulatory requirements.
- On site approximately 8-10 days per month.
- Can be home or office based.

YOUR QUALIFICATIONS / SKILLS:

- Fluent in French and professional proficiency in English. Dutch is an asset.
- Bachelor's Degree in Life sciences.
- Good understanding of clinical trials and current knowledge of ICH-GCP.
- Detail oriented and strong organizational and interpersonal skills.
- Demonstration of flexibility and professionalism.
- Good computer skills.
- Excellent communicator and a real team player.
- Full driving license and willingness to travel on regular intervals nationally and internationally.

If you want to join our team, you may apply for this position by sending your CV and application to **hr@cellaion.com.**

For information, resumes and application letters received will be retained as long as the employment's offer is valid and will be destroyed as soon as the position is filled. We will contact you in case we wish to keep your CV after the recruitment period.