Osivax is a clinical-stage biotechnology company that uses its oligoDOM™ technology platform to **develop innovative vaccines**. Osivax's main project is a universal influenza vaccine that aims to revolutionize the prevention of seasonal influenza, currently in **Phase 2a**. Osivax is using this same technology to develop a broad-spectrum vaccine against SARS-COV-2, its variants or a new coronavirus pandemic.
For more information, please visit their website : www.osivax.com

Osivax has offices in France (Headquarters in Lyon) and Belgium (Affiliate in Liège). It is a growing company with over 40 employees. Their offices in Liège host about 10 employees including Clinical Operations and a Quality Control laboratory.

As part of the development of their clinical trials in Europe and worldwide, and to strengthen their clinical team in Liège, we are looking for a:

Clinical Trial Assistant (M/F)

RESPONSIBILITIES

Reporting to the Clinical Operations Manager, your role is to **provide administrative and technical support, including regulatory activities linked to EU and US to the Clinical Operations Team** and assists them with the **in-house organization** and the **management of Clinical Trial activities**. You will achieving successful delivery of the Company's clinical activities by meeting company and regulatory requirements according to time, quality/scope and budget constraints, in coordination with other stakeholders in the clinical and other departments, vendors or subcontractors.

Your main responsibilities are:

Trial Management:

- Maintains tracking information and reference tools for clinical trial activities.
- Assists with coordination of meetings and travel arrangements.
- Attends team meetings and prepares accurate meeting minutes and log of action items.
- Provides support for trial budget follow-up.
- Maintains oversight of the purchase order process for clinical trial supplies and services, from set-up to reconciliation, as well as the processing of study invoices.
- Coordinates the ordering, packaging, shipping and tracking of clinical trial supplies and materials.
- Contributes to the overall quality of the clinical trials and key deliverables to be met
- Administrative office support.

Trial Documentation:

- Responsible for Trial Master File (TMF) management from creation to archiving, under the Clinical Project Manager's accountability.
- Supports Clinical Operations Team by handling other Trial documentation (Essential Documents, training records and other relevant documentation).
- Supports the Clinical Project Manager (CPM) with translation of Clinical Study documents.
- Participates in the preparation of audits / inspections.
- Makes recommendations for process improvement and efficiencies.

Regulatory Affairs:

- Performs final editing and formatting of regulatory documents (Protocol, Investigators' Brochure, DSUR, Clinical Study Report, etc.).
- Supports CPM with the Competent Authority and Ethics Committee submissions of clinical studies and related amendments.
- Maintains tracking information and reference tools with support of Regulatory for clinical trial activities linked to EC and Competent Authorities requirement.

Quality Assurance:

- Contributes to continuous improvement of Clinical Operations Quality System and Regulatory: Maintenance and development of Standard Operating Procedures and other quality documents (standard forms, etc.).

PROFILE

- Short or long cycle of education in life-science or healthcare related is desired.
- At least **2 years of relevant experience** in clinical trial secretary in Pharma, Biotech or CRO.
- Basic knowledge related to **ICH/GCP Guidelines** and applicable local regulation.
- Experience on the different stages of Clinical Trials (set-up, follow-up & closure) is an asset.
- Experience as regulatory assistant is an asset.
- You have good communication and organization skills, with a very high accuracy.
- You are flexible, hands-on, proactive, eager to learn and have a good sense of responsibility.
- **Fluent in English (boteh written and spoken)**. Speaking French or Dutch is an asset.
- Proficient in Microsoft Office (Word, Excel, PowerPoint).

OFFER

- **A permanent contract** and an attractive salary package in line with the position responsibilities and your experience.
- The opportunity to make a real difference in a vaccine development biotech company.
- Joining an international fast-growing team, supportive and collaborative.
- Individualized support and increasing autonomy.
- Flexible working hours, with an open, relaxed atmosphere.

INTERESTED?

Please send your CV together with an adapted cover letter to **mnavez@osivax.com**

YOUR APPLICATION AND
RELATED INFORMATION WILL REMAIN
STRICTLY CONFIDENTIAL.

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