Clinical research and biology affairs associate – Pharma/Medical devices

- Full time, 100%
- Based in Lausanne (Biopôle Epalinges and EPFL) – travel time: up to 30%
- 1-year contract, possibly renewable for a total of 2.5 years

Volumina Medical is a start-up, spin-off of the Swiss Federal Institute of Technology (EPFL), active in the field of medical devices. The company develops breakthrough innovations for plastic and reconstructive surgery. The first product is an implantable biomaterial and targets the regeneration of soft parts of the human body which are damaged due to ageing, tumor excision, genetic malformation, or trauma. In the framework of a collaborative project together with the CIBM (Center for Biomedical Imaging) at EPFL, we are looking for a highly motivated **clinical research and biology affairs associate** to join our clinical and biology team and contribute directly to the clinical validation of our products for tissue regeneration.

The main responsibilities of the candidate will be to support clinical and biology affairs for clinical and R&D projects in collaboration between the CIBM and Volumina Medical. You will participate to in vivo experiments, analysis of biological samples. Your missions will also include the writing of biology reports, white papers and scientific documents, as well as clinical documents to be submitted to competent regulatory and medical authorities for conducting clinical research. You will perform clinical literature searches, literature searches about biological mechanisms and interact with KOLs and plastic surgeons and dermatologists. You will also participate to the optimal implementation of the clinical studies under the supervision of the clinical affairs manager.

The primary activities include but are not limited to:

Biology activities:

- Perform *in vivo* experiments to understand the *in vivo* biological process taking place in the biomaterial (including participation in animal experiments, sample collection and processing, collection and analysis of technical and scientific data)
- Perform cell culture experiments
- Manage biology projects, interact with different teams to achieve the objectives of the project in a timely manner
- Perform literature research
- Write experimental plans and implement them
- Document all results according to guidelines and present results to the team

Clinical research activities:

- Perform clinical study site management/monitoring activities in compliance with ICH-GCP, Sponsor SOPs, Local Laws & Regulations, Protocol, Site Monitoring Plan and associated documents
- Perform remote and on-site monitoring & oversight activities to ensure that the data generated at site is complete, accurate and unbiased;
- Conduct site visits (validation visits, initiation visits, monitoring visits, close-out visits, etc.) and document activities in reports in a timely manner.
- Collect, review and monitor the required regulatory documentation for study maintenance and study close-out
- Communicate with Investigators and site staff on issues related to protocol conduct, recruitment, retention, protocol deviations, regulatory documentation, site audits/inspections and overall site performance
- Write clinical reports
- Participate to literature watch in the field of dermatology and aesthetic medicine

Other activities :

- Participate to preclinical validations on ad hoc basis, to support the preclinical affairs team when needed.
- Interact with external suppliers and identify new stakeholders for specific activities in relation with biological and/or clinical affairs.

Qualifications :

- Master's Degree of PhD in Biology (immunology, cell biology, animal experimentation, large animal experimentation) or in subject with a natural science background
- Animal experimentation license is required
- Initial direct site management (monitoring) experience in a (bio)pharmaceutical company or CRO is a plus
- Ability to travel approximately up to 30% of working time
- Good understanding of clinical research, phases of clinical trials, current GCP/ICH & swiss clinical research laws and guidelines
- Good knowledge of dermatology and aesthetic medicine clinical studies
- Ability to understand and analyze data/metrics and act appropriately
- Fluent English knowledge, both written and spoken. French or Portuguese knowledge is advantageous
- Strong patient focus; demonstrated ability to translate science into an easy to communicate language
- Effective time management skills and problem-solving skills
- Ability to work highly independently across multiple protocols
- You are disciplined and care about details
- You enjoy working in a multidisciplinary team and having interactions with others

We offer :

- A dynamic and stimulating work environment, between a leading institution of EPFL and an innovative start-up clinical stage Company
- The opportunity to collaborate with internationally recognized experts in the field of dermatology, plastic and reconstructive surgery in Europe, US and other countries
- The opportunity to express your talents and grow with the team
- The integration into an interactive team, where you can propose ideas
- To contribute to improve the life of millions of patients

Join us to become an essential part of our exciting journey in developing ground-breaking innovations!

Please send your full application (CV, Motivation Letter, work certificates, references and any relevant additional document) to:

- Gilles Bioley (gilles.bioley@volumina-medical.ch)
- Amélie Béduer (amelie.beduer@volumina-medical.ch)

Please indicate « Clinical research and biology affairs associate" in the subject of your email message.

Deadline for application: April 1st, 2024