Oloker Therapeutics is a biotechnology start-up dedicated to the discovery, development and commercialization of cellular therapies for the treatment of cardiovascular disease. Our mission is to bring to light new innovative medical therapies that can improve patients' lives through extensive scientific research and in-depth knowledge of the patient and his needs.

The "CPCPlus" technology to isolate a subpopulation of Cardiac Pro-angiogenic stromal Cells for cell therapy in Refractory Angina

Oloker's innovative technology consists of 1) a proprietary method for cardiac cell manufacturing and 2) a proprietary human cardiac pro-angiogenic, CPC product (CPCPlus). In particular, the manufacturing process include an innovative fully GMP-compliant high-efficient and cost-effective scalable method to isolate CPC both in autologous and allogenic settings. CPCPlus is therefore classified, according to EMA guidelines and EU legislation, as Advanced Therapy Medicinal Product (ATMP) specifically conceived to exert a potent angiogenic effect to the ischemic myocardium and with high immunomodulatory capacity. The invention tackles the unmet clinical need of a specific subset of patients with advanced coronary artery disease who are considered no longer suitable for state-of-the-art cures by means of medical therapy and conventional revascularization techniques (bypass surgery/coronary stenting). This population of no-option patients experience a dramatically poor quality of life due to so called "refractory angina". Our development plan is conceived to obtain regulatory approval of our invention to be tested as a therapeutic agent in a Phase I (safety/preliminary efficacy) clinical study in RA patients . Based on the current project status, the CPCPlus development plan firstly includes the pre-clinical experiments in small and large animal models in order to validate the angiogenic potency of CPCPlus in the context of chronic myocardial ischemia. The second part comprises the GMP manufactured CPCPlus validation with the creation of a master cell bank for allogeneic CPCPlus donor. The CPCPlus platform can subsequently be exploited to expand the possible clinical applications to other cardiovascular ischemic and non-ischemic disease.

A position of **Regulatory Affair specialist** is available in Oloker Therapeutics c/o Department of Experimental Oncology European Institute of Oncology

Tasks & responsabilities:

- Manage/direct the preparation and submission of the IMPD for the first-in-man (FIM) clinical trial to the Belgian regulatory authority.
- Collaborate with the internal research team to ensure successful project execution according with internal SOPs and ATMP-specific guidelines.

- Participate in meetings with foreign consultants to ensure compliance with regulations.
- Contribute to business process optimization activities to reduce waste and ensure efficiency.
- Continuously develop and deepen regulatory expertise through interaction with national and international consultants.
- Collaborate with external suppliers to obtain the technical documentation to perform the activities.
- Monitoring of regulatory requirements and guidelines to ensure compliance with changing regulations.
- Participate in meetings with investigators of the FIM trial to ensure the correct implementation of activities.
- Archive dossiers and regulatory documents.

Requirements:

- Bachelor's degree (or higher) in Science, Regulatory Sciences, Pharmacy or similar disciplines.
- RA Master's degree preferred.
- Experience in regulatory affairs.
- Knowledge of regulatory requirements and guidelines for the development of advanced medical therapies and applications for authorization.
- Excellent written and spoken English.
- Basic knowledge of GxP.
- Good time management skills to handle multiple activities while respecting deadlines.
- Strong communication skills with internal and external teams.
- Effective problem-solving skills.
- High level of motivation, initiative, flexibility.
- As a person, you like to be challenged, are organized and reliably independent, show attention to detail, enthusiasm and commitment.

The initial appointment will be one year, renewable with the possibility of converting to a permanent contract.

The work location will be at Department of Experimental Oncology European Institute of Oncology, Via Adamello 16, 20139 Milano, Italy.

Candidates interested in the position shall send a letter to Dr.ssa Elisa Gambini (egambini@oloker.com) detailing their experience and providing an updated CV. Reference letters are encouraged.

Salary will be commensurate with experience

- ORGANISATION/COMPANY: Oloker Therapeutics, Srl
- RESEARCH FIELD: Biological sciences
- RESEARCHER PROFILE: Regulatory Affair
- LOCATION: Italy › Milano
- TYPE OF CONTRACT: Fixed-term contract
- JOB STATUS: Full-time
- HOURS PER WEEK: 40