OMEICOS Therapeutics GmbH as a clinical-stage biotech company is developing oral, first-in-class, small molecules for the prevention and treatment of cardiovascular and ophthalmic diseases. OMEICOS exciting platform technology is based on proprietary synthetic analogues of omega-3 fatty acid metabolites, exerting cell-protective pathways with potential applications in cardiovascular diseases, multiple eye disorders and several other indications.

As an ambitious team we are looking for a

Clinical Project Manager (m/f/d)

Your responsibilities:

- Ensure studies are carried out according to the study protocol, SOPs, EMA/FDA, ICH guidelines, all regulation and national law, and study-specific manuals and procedures.
- Develop and administer study budgets.
- Negotiate and manage the contracts, budgets for third party vendors, including CROs. Work closely with our financial department to accurately track spend and monitor cash flow forecast for clinical plan delivery.
- Identification and hiring of appropriate CROs and third-party study vendors, together with the rest of the clinical team.
- Oversight drug product activities.
- Oversight performance of CROs, third-party vendors, and CRAs (internal and external) to ensure compliance with study protocol and in accordance with scope of work and corporate timelines.
- Write or contribute to preparation of clinical protocols, amendments, informed consent forms, data management plan, statistical analysis plan, and any other clinical research related documents.
- Contribute in preparing Clinical Study Reports and annual safety reports.
- Review and/or submission of ethics committee/regulatory documentation.
- Coordinate intern CRA activities.
- Perform clinical data review of data listings and summary tables, including query generation.
- Establishing and track clinical timelines and appropriate performance metrics.
- Review key study quality metrics (e.g., eligibility, primary endpoint, data, etc.) and determine appropriate action in conjunction with study team (autonomy may vary with experience).

Your professional experience and personal skills:

- University degree in Life-Science or similar qualification
- Extensive experience of at least 4 years in clinical research and proven background in managing of clinical trials
- Experience in biotech company or CRO would be welcome
- Strong familiarity with all clinical documents, in particular experience in data management field would be an advantage
- Ability to complete tasks in an accurate, timely manner and effectively manage multiple tasks
- Sense of urgency, ability to prioritize tasks and escalate issues according to their relevance
- Ability to identify issues and problems and address them by their root cause in a timely manner
- Experience in Risk Management

- Financial understanding and ability to manage a budget
- Excellent knowledge of Good Clinical Practice requirements, and global clinical development processes.
- Strong communication and interpersonal skills as well as demonstrated hands-on mentality
- Ability to motivate both individuals and a team
- Excellent English skills in written and spoken; fluency in German would be an advantage
- Passion for lab work as well as project management
- Excellent knowledge of *immunological cell types and inflammatory signaling pathways*
- Ideally experience with GLP environment, SOPs and QM system as well as pharma product driven research
- Excellent communication and organizational skills
- Assertiveness, conscientiousness and high social competence
- Very good command of spoken and written English
- Very good knowledge of MS Office, GraphPad Prism, etc.

OMEICOS offers:

- Full-time employment, initially limited to one year with the prospect of permanent employment.
- Employment in a dynamic biotech company with flat hierarchies and a strong team culture
- Direct involvement in company's development program
- Professional environment as member of a scientific driven team
- Workplace in a very modern scientific hotspot, surrounded by nature, where a good canteen is available as well as the possibility in the free time to attend different sport trainings and events.

Your application:

If you are looking for a new career challenge, we are looking forward to receiving your application including your earliest possible starting date and salary expectations.
Please send your application exclusively via email to the attention of Dr. Luciana Summo, info@omeicos.com

OMEICOS Therapeutics GmbH
Robert-Rössle-Straße 10
13125 Berlin