Polyneuron Pharmaceuticals AG
Hochbergerstrasse 60C
CH-4057 Basel

Polyneuron is a growing Basel-based biotechnology company active in the area of autoimmune disease treatments. The company was founded in 2014 as a spinout company from the University of Basel to develop novel treatments to combat immune disorders using its Antibody-Catch™ technology platform. The company currently employs 10 people and has raised a significant amount in equity funding from top-tier venture capital funds. The first dysimmune neuropathy program will enter the clinical phase in 2020 and further programs are planned to follow. To support our clinical development team, we are currently looking for a

Clinical Trial Manager (100%)

You have a university degree with a medical or scientific background. You have a minimum of 5 years' experience in clinical trials management (particularly phase I and II), preferably in the area of small molecules and/or biologics and proven experience with orphan disease clinical trials in Europe or in a transatlantic environment. You have good knowledge of ICH, FDA and EMA GCP guidelines and regulatory requirements for clinical submissions. You are used to work with CROs and to manage external resources in an international environment.

Your responsibilities will be to:

- Design, revise, and maintain relevant protocols, reports, SOPs, and any other relevant documents for the conduction of the study (protocol, IB, CRF, IC, Insurance in compliance with GCP);
- Select, supervise and coordinate CROs;
- Identify and coordinate clinical product related activities such as: drug supply to clinical study, labeling, packaging, required preclinical data, toxicology, etc.;
- Organize, implement, manage, and monitor clinical trials (coordination of clinical sites, CROs, external sources, IMP supply, data management activities) while assuring compliance with GCP and any applicable national regulations;
- Support in setup of contracts with external sites such as hospitals, universities, CROs;
- Manage budget and resources of task-related clinical trials;
- Prepare and receive study approval from EC and support CA approval applications;
- Author, revise and/or update all study-related documents, reports, the SOPs, Work Instructions and additional relevant documents;
- Oversight of all trial files, including the TMF to ensure audit-readiness;
- Implement SOPs in house to support the pre-clinical development.

You are an efficient and enthusiastic team player with:

- Working experience in conducting clinical studies in life science industry
- Previous start-up, small company experience
- Excellent communication and presentation skills
- Ability in maintaining deadlines, ability to identify and mitigate risks, solve problems
- Strong operational, organisational, and documentation skills
- Fluent in English, German and French would be an asset
- Willingness to travel

Working place is Basel. We offer a competitive remuneration package. Should you wish to join a team of R&D professionals and participate in the development of novel therapeutics against autoimmune diseases, please contact us, we are looking forward to meeting you.

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