NEXILIS
Improve implant anchorage

15.11.2021

Open Position Nexilis AG

Nexilis AG is a Swiss start-up company located in the Futuro Technopark, Liestal, Basellandschaft. Currently the team is focussing on the development of the ISS (Immediate Stabilization System) technology, an innovative medical device system that enhances orthopaedic implant fixation in spinal fusion and vertebral fracture surgeries. The application of ISS elsewhere in the body has the potential for broader market access. Nexilis has a clinical program underway and is initiating activities for market entry. For this purpose, Nexilis is seeking to hire a motivated, adaptable, and collaborative individual with a "can do" attitude who is ready to make a positive impact. The following position is available:

Clinical Research Manager

The position

The Clinical Research Manager reports to the Medical Director and is responsible for working cross-functionally to set up and oversee the conduct of company-sponsored clinical trials designed to support regulatory goals and customer adoption of the Immediate Stabilization System. The position is a 60-100% employment and can be assumed at any time, preferably in January 2022. While the corporate office is based in Liestal, Switzerland, candidates based in Germany are encouraged to apply given the proximity to study centers in Germany.

Accountability and key responsibilities

- Actively participate in the development and review of clinical trial documents and manuals, including but not limited to clinical investigation plan, amendments, patient information and informed consent form, case report forms, statistical plan and reports
- Assure compliance with protocol requirements, national and international regulations and ICH-GCP
- Manage Trial Master File
- Track and report on progress of clinical studies, e.g. track patient enrolment and ensure the timely, accurate and complete collection and transfer of study data and regulatory documents
- Coordinates clinical budget and related pricing strategy services for the purpose of executing a clinical trial or ancillary services agreements
- Participate in clinical and regulatory meetings, safety monitoring boards, CRO meetings
- Develop and execute cross-functional plans for the project/clinical study
- Manage relationships with CROs, investigators and KOLs
- Assure compliance with the QMS of the company and support the creation and correct filing of QM documents
- Assist in the planning and execution of clinical projects while adhering to budget, scope and schedule requirements
- Assist in identification and selection of appropriate clinical CROs and third-party study vendors
- Assists in identification, evaluation and selection of investigational sites
- Assist in clinical literature/data searches and reviews, generate data listings and summary tables
- Support corporate initiatives in marketing, business development or medical affairs as required.
- May be responsible for coordinating efforts for KOL events within the trials and at conferences both within the company and through a variety of vendors

Qualifications and Experience

- Master's Degree or equivalent in the field of medicine/biology/health sciences or related
- Minimum 2 years of experience in the conduct and management of clinical trials in Medtech, Biotech or Pharma industry
- Strong knowledge of ICH GCP and ISO 14155
- GCP III course certificate
- Strong skills and experience in project management, accurate working habits
- Strong analytical skills
- Critical thinking, open for new solutions and out-of-the box-perspectives
- Excellent verbal and written communication skills in English and German
- Proficient with Microsoft Office programs, good knowledge of Adobe Acrobat DC and Endnote is a plus
- Team player and group contributor
- Ability to think on his/her feet, has preferably already small company experience
- Can-do attitude

We offer to you

- Possibility to contribute cross-functionally and be part of a small motivated team that will establish the future success of Nexilis
- An opportunity for professional development with a versatile and challenging task in a start-up environment
- Meaningful work that will have an impact on patient's lives
- International work with international colleagues
- An honest, and open working environment
- Flat hierarchies and short decision-making paths
- Flexible working hours and home office options
- Five weeks of vacations
- Performance oriented remuneration including participation in an employee incentive program
- Job sharing options

Interested and motivated candidates are encouraged to submit an application to:
Nexilis AG, Human Resources, Gräubernstrasse 16, 4410 Liestal
+41 61 922 05 63, samuel.kallmeyer@nexilis.ch, www.nexilis.ch

For additional information or to have any questions answered, please also connect with Samuel Kallmeyer by email or by phone.