CUTISS AG, a biotech company spin-off of the University of Zurich (UZH), focuses on the development of personalized bioengineered skin graft products for the treatment of skin defects. Its lead product denovoSkin™ has successfully completed Phase I in paediatric patients. Clinical Phase II studies are underway in Europe and Switzerland.

For our expanding headquarters in Schlieren, Switzerland, we are currently seeking as soon as possible a motivated and experienced

Clinical Trial Associate 80-100%

The Clinical Trial Associate will support the clinical department of CUTISS in implementing, managing, and maintaining the activities and processes related to the clinical trials with autologous skin substitutes. Activities are performed according to internal SOPs, GCP guidelines, Swiss law, ICH guidelines, and according to local requirements of study sites.

Description of Responsibilities

Support the tasks of a clinical trial specialist:

- Clinical trial management including management of CROs, IDSMB, OCs
- Support all administrative aspects around clinical trials
- Manage drug supply by communication with sites, CROs, and manufacturing team
- Provide investigators and study teams on-site and remote trainings and maintain relationship
- Creating and implementing study-specific clinical training and monitoring tools
- Provide support to study staff to ensure smooth functioning and monitor delivery of all study activities

GCP Documentation:

Support the preparation of documents necessary for study initiation, execution, and termination.
Preparation, revision, and management of project-specific documentation, such as:

- Standard Operating Procedures (SOP's)
- Working Instructions (WI)
- Risk analysis
- Change requests
- Electronic case report forms
- Study Protocols, patient information, and patient informed consents

Regulatory Affairs:

- Actively participate in the compilation of clinical trial submission dossiers, change requests, safety reporting

Required Experience and Skills

- B.Sc. in a biological field or healthcare (e.g. biology, biotechnologies, biomedicine, nursing) or a comparable education
- Minimum of 1 year active clinical trial experience
- A broad understanding of GCP and regulatory requirements, accredited GCP course is a plus

- Ability to work in a fast-paced and ever-changing environment, as well as the proven track record of working effectively in diverse teams involving multi-functional disciplines.
- Able to communicate effectively at all levels and present complex and/or new ideas with clarity and simplicity.
- A desire to be part of a highly innovative company aimed at transforming the lives of people with serious diseases, their families and society.
- Precise and accurate work
- Excellent oral and written communication and presentation skills
- Fluent in English (written and spoken)

Desired Skills and Experience

- German, Italian, Dutch and French are a plus

Work Environment

- Open Office environment

We offer

- High pace start-up environment
- Flexible working hours in arrangement with Supervisor
- Competitive benefit package
- A young and dynamic team
- 5 weeks holidays (at 100% work quota)

Are you interested?

Please send us your complete application including the following documents:

- Motivation letter
- Curriculum vitae
- References

We look forward to hearing from you soon!