CUTISS AG is a pioneering company in precision regenerative medicine, focused on transforming skin surgery. Our flagship product, denovoSkin™, is a bio-engineered skin graft aimed at improving the quality of life for patients with severe skin injuries. We are also advancing VITICELL®, a cell therapy-based treatment for vitiligo and dyspigmented burn scars.

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

Clinical Trial Manager (f/m/d) 100%

who will support our clinical team by managing clinical trial operations and can start immediately.

As a Clinical Trial Manager at CUTISS AG you will play a pivotal role in overseeing and managing clinical trials from start to finish, ensuring compliance with ICH GCP guidelines, EMA/FDA, Swiss and other local regulations, and the company's SOPs.

Your main duties

- Ensure all clinical trials comply with regulatory requirements (e.g., FDA, EMA) and GCP guidelines.
- Manage and oversee the overall execution of a Phase 2 and 3 study
- Design and draft clinical trial protocol, timelines, budgets, and resource plans.
- Oversee regulatory submissions for assigned study/ies
- Provide an oversight of the CRO and other clinical vendors
- Develop and draft study plans, manuals, systems set up (EDC, IWRs, eTMF, RACT etc.) patient facing documents (including ICFs) and training documents
- Select, qualify and oversee clinical trial sites. Train and support site personnel and ensure adherence to study protocols.
- Lead and/or support organization of Investigators Meetings and Investigators trainings
- Assist in planning and operational execution of IMP supplies
- Oversee data collection, entry, and validation processes to ensure data integrity and quality.
- Review monitoring visits reports
- Periodically review the protocol deviations and risks and identify the trends, quality concerns and other areas for improvement and implement mitigation strategies.
- Monitor on trial progress and address issues promptly.
- Provide updates of study status to senior management
- Support, train and collaborate with other team members and CUTISS departments.
- Supervise the clinical team members
- Serve as the primary point of contact for all trial-related communications.

Required Experience and Skills

- Bachelor's degree or equivalent qualification in life science or healthcare (Masters' degree is preferred)
- Minimum of 5 years of clinical trial management experience within the CRO/pharmaceutical industry with proven strong leadership (Phase 2 and 3)
- Working knowledge of ICH-GCP, FDA, EMA and other regulatory requirements
- Working knowledge of EU CTR and CTIS preferred

- Experience with biologics is a plus
- Able to communicate effectively at all levels and present complex and/or new ideas with clarity and simplicity.
- Ability to work independently and in a team environment
- Precise and accurate work
- Excellent oral and written communication and presentation skills
- Fluent in English (written and spoken)

We offer a unique opportunity to be part of a young and motivated project team with the vision to improve patients' quality of life. This interesting and challenging role will allow you to further develop your skills in a biotech start-up environment and engage with international partners and clinical trial centers. In summary, you can expect:

- A high pace start-up environment
- Flexible working hours in arrangement with the Department Manager
- A young and dynamic team
- 26 days of vacation/year

Are you curious to find out more?

If you are interested in applying for this position, you may send your complete application in **English**, which should include the following documents:

- One-page motivation letter
- Curriculum vitae
- Copies of degrees and references

by using the following link:

Apply Online

For further information, please contact our HR partner HC Solutions, Yagmur Kutbay or Annika Danielsson.

HC Solutions AG | Zollikerstrasse 153 | 8008 Zürich | 044 915 12 12 | www.hcsolutions.ch