CUTISS AG, a Life Science company spin-off of the University of Zurich (UZH), focuses on the development of personalized regenerative medicine products for the treatment of skin defects and skin pigmentation disorders. Its lead product denovoSkin™ has successfully completed Phase I in pediatric patients. Clinical Phase II studies are underway in Europe. The company has also launched a program on vitiligo treatment.

To set-up, manage and complete clinical development projects, while providing full oversight of the operational Clinical Development Team and its operational activities we are currently looking for a

Director of Clinical Operations (DCO) 50% - 100% (f/m/d)

For this position we are looking for an organized Director of Clinical Operations to set-up, implement and oversee clinical development projects, and to ensure that all quality standards and regulatory requirements are met in a timely fashion. The DCO reviews budgets, makes changes where necessary, and outlines projects together with the investigators and clinical development team. The DCO regularly interfaces with investigators and investigational site staff and oversees all outsourced activities of professional service providers. The candidate is expected to be flexible with a “Can do” attitude and with a sense of client/service-oriented thinking and the ability to prioritize tasks while adding value to the project(s)

Your Responsibilities

- Creation, implementation and management of the clinical development project plans in conjuncture with the CMO and relevant disciplines from phases I ("Proof of concept") through III clinical studies
- Assures the registration of studies in relevant Clinical Study Registries
- Manages approval of a clinical study by the relevant regulatory agency (e.g. EMA, FDA) and by the relevant Institutional Review Board/Ethics committee (IRB/IEC)
- Assures that a study is conducted in full compliance and adherence to ICH/GCP and relevant regulatory requirements, including the conduct of (internal/external) audits of PSPs
- Assures that study specific activities are conducted in accordance with the Quality Management System
- Assures that all study-related forms are available, including case report forms (CRFs), regulatory documents, trial master file and investigator site file, monitoring tools, clinical study contracts, letters of indemnifications, data validation plans etc.
- Responsible for the creation of patient information leaflets and informed consents
- Internal review and approval of clinical development project plan, study-related documents, contracts etc.

- Management of investigational medicine product (IMP) supplies and logistics including labelling and shipment
- Identification, recruitment and management of new Professional Service Providers (PSPs) and other vendors/contractors
- Organization and management of Investigator or Clinical Advisory Meetings, as well as the study-specific Data Safety Monitoring Board (DSMB), Adjudication Committee or Steering Committee
- Support in publication planning of scientific publications
- Provides training to relevant Staff involved in the study on study-specifics

Your Profile

- Master degree of clinical administration, medical science, or related fields, PhD highly preferred
- A minimum of 12 years proven experience in a Clinical Study Director or other clinical managerial positions
- Proven track record of managing a clinical development and operational team
- Experience in project management and proven track record of setting-up, conducting, managing and concluding clinical studies of IMPs, preferably biologics, from "A to Z"
- In-depth knowledge of policies and regulations in the clinical field
- Excellent communication, interpersonal and leadership skills
- A "Can do" attitude and the ability to prioritize tasks while adding value to the projects
- English is mandatory, German, French or Italian knowledge is an advantage
- Valid work permit for Switzerland

We Offer

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

Starting date: October 2022 or as soon as possible
Place of work: 8952 Schlieren

We are looking forward to receiving your application, including CV, motivation letter, references and diplomas.

Please note that we exclusively accept applications submitted through our online application portal. Applications via e-mail cannot be considered.

Please note that we do not consider candidate dossiers from recruitment agencies.

Apply now

For further information, please contact our external HR partner HC Solutions, Annette Corona or Annika Danielsson.

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www.hcsolutions.ch