
Our client is a renowned privately held pharmaceutical company headquartered in Switzerland and located in 31 countries around the globe. The company develops and manufactures products in the area of hematology, immunotherapy and critical care. More than 10.000 employees benefit from a challenging and rewarding work environment that empowers people to gain important achievements for patients worldwide.

The location in Vienna is the company's largest manufacturing site and also a very successful research base. For this location we are currently hiring a:

## Lead Clinical Research Associate (f/m/d)

In this position you will be responsible for the quality of study data and for ensuring that studies are carried out according to study protocols, SOPs, ICH/GCP and regulations. You will be responsible for sponsor oversight in terms of monitoring (conducted by CRO/external CRAs), co-monitoring, electronic Trial Master File (eTMF), laboratory, data management and other areas essential for data quality.

**Key Responsibilities:**

Monitoring Oversight:

- review of monitoring visit reports
- establish and track appropriate performance metrics in terms of monitoring
- provide guidance and training to CRO/external CRAs
- ensure quality of eTMF, conduct regular quality reviews
- present at and provide support for investigator meetings/CRA trainings

Co-Monitoring:

- develop and maintain good working relationships with investigators and study staff
- co-monitor clinical sites for adherence to protocol and GCP
- identify, select, and monitor performance of investigational sites and CRAs
- provide support for preparation of sites for audits / regulatory inspections

Data Quality:

- perform regular clinical data review (of specified data listings and summary tables)
- review reported protocol deviations
- support the process of data cleaning, data lock and preparation of clinical study report
- support set-up and development of eCRF and IRT

Vendor management:

- main point of operational contact for CRO Lead CRA/clinical monitoring team
- oversee and manage central laboratory and clinical trial supplies
- oversee and manage performance of other third party vendors

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**Required qualifications and experience:**

- Medical-pharmaceutical, scientific or similar background, preferably academic
- Work experience in the pharmaceutical industry or CRO industry
- Previous work experience with Phase 2 or 3 studies
- A minimum of 5 years' experience as a Clinical Research Associate
- Extensive co-monitoring experience
- Problem-solving abilities, excellent communication skills and manners
- Strong interpersonal skills
- Ability to work efficiently, independently and in a team environment
- Precise workstyle and deadline accuracy
- Willingness to travel up to 35%
- Excellent German language skills and fluent in English; both written and oral
- Good IT skills

**The offer:**

- A highly professional and international environment and a company culture fostering respectfulness and mutual appreciation.
- Flexible working hours, fulltime 38 hrs/week.
- The minimum monthly salary for this position is € 3.389,68 (14 times) based on the Austrian collective agreement chemical industry. Depending on your qualifications and professional experience the salary may be higher.
- The position is home-office based.

If you're interested in joining an exciting company, please send your CV and your letter of motivation. We are very much looking forward to receiving your application.

Not exactly the position you are currently looking for? Please feel free to forward it to friends or colleagues who might be interested in our offer.

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