Towards Safer Therapies

In the heart of the science and business location Heidelberg, GeneWerk GmbH has found ideal conditions for steady growth. For six years, the company with its experienced and motivated staff has been offering NGS-based molecular biological analysis services, especially for companies in the pharmaceutical, life sciences and biotechnology industries. The aim is to advance the development of innovative therapies such as gene and immunotherapies through comprehensive safety analyses. Safe and effective therapies are thus within reach for many diseases.
In addition to pure research contracts and preclinical testing, the analyses also include examinations of patient material as part of clinical trials. In particular, the guidelines of the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) must be observed.
With the help of the investor Ampersand Capital Partners, GeneWerk will push ahead with its expansion in the USA in order to better serve the rapidly growing American market.
We are looking for a dedicated individual to join a great team as soon as possible:

Quality Manager (GCP/GLP) (m/f/d)

Spectrum of Tasks

- Responsibility for the company's Quality Management System;
- Assisting with the expansion and future certification and accreditation tasks;
- Performing internal audits in compliance with GCLP, GCP and GLP guidelines;
- Involvement in audits from external clients and agencies;
- Active participation in the qualification of devices, systems, and suppliers;
- Organizing and overseeing employee training;
- Creation, revision, and review of documents such as SOPs and Work Instructions;
- CAPA, Deviation, Risk Analysis and Change Control Management;
- Participating in training courses and quality related marketing activities;
- Communicating with national and international pharmaceutical and life science customers/auditors;
- Active participation in the quality assurance of ongoing laboratory and data analysis processes.

We are looking forward to receiving your comprehensive application via e-mail to:

GeneWerk GmbH, Im Neuenheimer Feld 582, 69120 Heidelberg, Germany | personal@genewerk.com

We are also happy to answer questions on the phone: +49 6221 42790-13 | Contact Person: Luisa Wassermann

Requirements

- Completed scientific studies in biology, biotechnology, medicine, pharmacy, or related natural/biological sciences;
- Several years of experience working within quality assurance, preferably in the Biotechnology or Pharmaceutical area;
- Knowledge of current international regulations for GCP/GLP with a minimum of two years direct experience;
- Experience with accreditation/certification procedures for GLP, or within the DIN-EN-ISO area are desirable;
- Experience with computerized systems validation, and cloud-based IT systems would be an advantage;
- Very good knowledge of German and English, both written and spoken required;
- Strong quality awareness;
- Work with integrity, dedication and have an outstanding work ethic;
- Ability to work in a team.

What We Offer (i.a.)

- Fixed salary; 30 days annual vacation;
- Flexible working environment (working via home office possible);
- Expanding quality department and the ability to help shape the future program;
- Professional and personal development opportunities;
- Pleasant working atmosphere within our international team.