

You are an experienced quality expert in a biotech environment, who loves the mix of strategic and hands-on work?

Heidelberg Pharma AG is a biopharmaceutical company based in Ladenburg near Heidelberg. Heidelberg Pharma AG is listed at the Frankfurt Stock Exchange in the Regulated Market/Prime Standard. Our main goal is to develop cancer therapies. Our focus is primarily on the ongoing development of ADCs, which are based on our innovative ATAC[®] technology whose payload consists of the active ingredient Amanitin.

We are looking to hire a

Head of Quality Assurance (f/m/d) GxP

in a permanent, full-time position for our location in Ladenburg or home based with regular visits to Ladenburg.

What awaits you:

The opportunity to question and, if necessary, redesign the company's already partially established quality assurance concept.

- You are responsible for all aspects of Quality Assurance including GCP and GMP activities.
- You ensure that Heidelberg Pharma's pharmaceutical drug research and development programs comply with applicable GCP and GMP regulations, guidelines, Standard Operating Procedures (SOPs), and current industry standards and practices.
- You are responsible for the preparation, maintenance and review of QA-relevant documentation.
- You manage GCP and GMP audit programs, develop and implement detailed audit plans and yearly audit schedules. You conduct internal and external audits, prepare audit reports and communicate findings and recommendations. You discuss audit and inspection findings with management staff to develop appropriate corrective and preventive actions, where appropriate.
- You work closely with non-Clinical, Clinical and Technical Development and other departments to ensure compliance readiness and inspection preparedness.
- You direct and/ or deliver all necessary GCP and GMP training for internal staff.

What we look for in you:

- You hold an academic degree in life sciences and have a minimum of 10 years of professional experience in the pharmaceutical/ biotech industry and at least 5 years of QA experience.
- A Quality Assurance professional certification is a plus.
- You have profound knowledge of GxP regulations, practices and trends pertaining to pharmaceutical product development, manufacturing, testing, and clinical development and operations.
- Additionally, you have experience with FDA or other Regulatory interaction.

- You are assertive, highly process-driven and solution oriented and you have the ability to work in teams as well as in matrix organizations.
- You possess an organizational and planning talent with excellent communication skills (written or spoken). You appreciate independent, structured and precise work.
- Very good Business and Medical English complete your profile.

What we offer:

This is a newly created position, where you will have the opportunity to develop your place in the team. You will report directly to the CEO.

- As part of an international team, you will contribute to the research and development of medicines against cancer. You can expect a professional working environment with highly motivated employees and a friendly and welcoming working atmosphere.
- We place great importance on giving you the opportunity to develop your potential and thus contribute to the success of our company. We support you with training opportunities.
- We care about the health of our employees: compatibility of family and career, company pension scheme, measures for company health management (e.g. additional preventive medical examinations as part of company health insurance policy, active break, bike leasing) as well as the possibility to continue working safely despite COVID-19 are of great importance to us.

Have we sparked your interest?

Then please send your detailed application exclusively by email and in one pdf to our human resources department at

jobs@hdpharma.com

Please specify your earliest possible starting date.

Only together can we slow down the global spread of COVID-19 and protect our society. Therefore, the first round of our interviews will be conducted via telephone or video. We strongly encourage you to continue to apply for a job with us and look forward to getting in touch with you!

Heidelberg Pharma AG
Personnel Department