## *We are looking for a Regulatory CMC expert in the field of Biologcis with a touch for pragmatic solutions.*

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 Antibody-Drug Conjugates (ADCs), which are based on our innovative ATAC® technology whose payload consists of the active ingredient Amanitin.

We are looking to hire a

# Regulatory CMC Lead (f/m/d)
# (Chemistry, Manufacturing, and Controls)

in a permanent, full-time or part time (approx.32 hours/ week) position for our location in Ladenburg or home based with regular visits to Ladenburg.

### What awaits you:

You will be the regulatory CMC lead for assigned development projects and provide regulatory CMC guidance and strategy from pre-clinical stage up to marketing authorization. Your field of activity includes further tasks:

- You define regulatory CMC content of regulatory application dossiers for drug development and marketing authorizations. In addition, you coordinate the preparation, writing and review of CMC-related documents and dossiers (e.g. M2 and M3 CTD documents for IMPD, IND, BLA, MAA, QOS, RFI responses, briefing books).
- You also plan, prepare and conduct all CMC-related aspects for interactions with competent authorities (e.g., FDA, PEI, EMA,) in the scope of drug development
- In addition, you are the contact person for external partners, e.g. development partners, competent authorities, CDMOs, consultants. Furthermore, you prepare and maintain DMFs to support our Licensees.
- You monitor the regulatory CMC landscape; analyze the impact of regulation changes for HDP projects and processes; you keep current with, review and interpret regulatory and scientific regulations and guidelines; communicate important changes and trends with relevant stakeholders.

### What we look for in you:

- You hold an academic degree in pharmacy, chemistry biology biochemistry or equivalent and have a minimum of 10 years of professional experience in the field of global Regulatory CMC in clinical development, registration and/or post-marketing for New Biologic Entities (NBEs), knowledge of New Chemical Entities (NCEs) is also a strong asset.
- Profound knowledge of CMC drug development (Drug Substance and Drug Product).
- Extensive experience in preparation and revision of regulatory CMC documents is required for this position.
- You have experience with the preparation and conduct of Health Authority meetings

- You can take a balanced view of a problem field and find pragmatic solutions in a highly dynamic environment.
- You can cope with unforeseen situations and can easily adapt to new situations and different dialog partners. You are also able to adapt your working hours to the situation.
- You have very command of English and German, both written and spoken.
- You enjoy working in cross functional project teams. And a high degree of communication skills round off your profile.

## What we offer:

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

- 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.

**Preferably, the first round of our interviews will be conducted via phone or video. We look forward to being in contact with you!**

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68526 Ladenburg