Do you want to work with us?
Then we should get to know each other!

we are looking for a…

Non-Clinical Drug Development Expert (m/f/d)

Full-time

Who we are and what we do

Founded in 1994, regenold GmbH is an international regulatory service provider with over 100 employees. We support clients worldwide in the development, approval and market access of pharmaceuticals, medical devices and in vitro diagnostics, cosmetics, food supplements and other healthcare products.
You can find more information on our homepage: www.regenold.com

Your responsibility, tasks

- Providing strategic non-clinical guidance to project teams covering a wide range of pharmaceutical products (small molecules, biologics, ATMPs, combination products)
- Planning of non-clinical drug development programs according to ICH M3, ICH S6, ICH S9 and other applicable guidance
- Acting as non-clinical expert in global agency interactions (e.g. scientific advice meetings)
- Management and monitoring of non-clinical studies
- GLP auditing of non-clinical CROs
- Toxicological evaluations of active ingredients, excipients, and impurities
- Preparation of non-clinical documentation for CTA (IB) and MAA (CTD modules 2.4, 2.6, and 4)
- Revision of non-clinical parts of product information texts (Summary of product characteristics, Patient information leaflet)
- Gap analyses of existing non-clinical documentation
- Due diligence for in-licensing candidates

Your education, skills, knowledge and experience

- PhD in life sciences, or degree in medicine, veterinary medicine or similar field
- Know-how in preclinical pharmacodynamics, pharmacokinetics and toxicology
- Practical experience in non-clinical pharmaceutical development (experience in non-clinical development of ATMPs or biological products is a plus)
- Relevant experience in pharmaceutical companies, biotechs, non-clinical CROs or regulatory authorities
- Knowledge of GLP and regulatory non-clinical requirements
- Experience within silico tools like QSAR or PDPK modelling is a benefit
- Ability to understand and to communicate complex non-clinical development scenarios
- Excellent written and oral communication skills in English
- Ability to work independently and manage multiple tasks simultaneously

Our value promise

- Customer and solution orientation - for us, this is the DNA of a good service provider
- Experience, expertise and worldwide networking in over 90 countries through the regulanet® network, www.regulanet.com
- Innovative and long-standing customers who are happy to recommend us to others
- a cross-team personal and active, lively teamwork
- an attractive, bright and modern working environment

What you get

- International **diversity** - in the team and in the projects
- Long-term **prospects** - for professional and personal **development**, we offer a wide range of tasks and **individually** tailored training opportunities right from the **onboarding phase**
- Flexibility, freedom and personal responsibility - through flat hierarchies, short decision-making processes and **family-friendly** working time models, with something for everyone …
- One of the most beautiful regions in Germany, also called the Toscana of Germany, on the edge of the Black Forest in the border triangle of Germany/ France/ Switzerland
- Remote work solutions possible upon agreement
- Attractive salary, company pension scheme, capital-forming benefits, JobRad, Hansefit, Corporate Benefits, Shuttle Transfer Freiburg-Badenweiler **and much more**

Did we make you curious?
Then we look forward to receiving your complete application to
perspectives@regenold.com
Contact Lynn Harwardt / +49 (7632) 8226-149
regenold GmbH / Zöllinplatz 4 / 79410 Badenweiler / www.regenold.com