

Formycon AG is one of the world's leading developers of biosimilars. With an experienced team comprised of more than 130 professionals, the company is able to span the entire value chain of biosimilar drug development, from market analysis and protein analytics, to the development of production processes, to clinical trials and the regulatory approval process.

To support our team in Martinsried near Munich, we are looking for suitable candidates for the following fulltime permanent position, to begin work as soon as possible

## **(Associate) Regulatory Affairs Manager (m/f/d)**

### **Your responsibilities:**

- Planning, writing and compilation of regulatory documents for Formycon's biosimilar development programs with focus on CMC for analytical development programs (e.g. method qualification/validation studies)
- Support compilation of documents for scientific advice requests, clinical trial applications and other regulatory documents
- Support submission process of scientific advices and clinical trial applications and interact with CROs and regulatory consultants
- Participation in project teams and regulatory point of contact for external partners, CROs and internal functional departments
- Review and approval of documents/plans/reports from CROs and internal functional departments
- Regulatory compliance check of documents and evaluation of change controls

### **Your qualifications:**

- Scientific background with bachelor or master degree preferably in biology, biotechnology, pharmaceutical sciences, chemistry or equivalent
- Ideally one or more years practical experience in either CMC RA area or compilation/submission of regulatory documents in the context of scientific advices/clinical trial applications
- Experience with biological or biosimilar products and knowledge of corresponding EMA/FDA guideline requirements would be of advantage
- Very good team player, result oriented, well organized, proactive, problem solver and able to work independently
- Creativity and enthusiasm for working in a dynamic fast growing biopharmaceutical company
- Fluent in written and spoken English required, German knowledge is desirable
- Proficient in MS-Office
- German work permit is mandatory

Bring us your skills and energy and shape your own career in a stimulating and open work environment. We are looking for highly motivated individuals who are ready to take on new challenges with enthusiasm and personal commitment. Working at Formycon means being part of a smart, innovative team with minimal hierarchy and opportunity to share your own ideas.

Have we sparked your interest? Then we look forward to receiving your application for employment through our online application portal. Please be sure to include all supporting documents, along with your earliest possible starting date and your salary expectations. We look forward to learning about you and the qualifications which you would bring to this position.

[Online Application](#)



**We Develop High-Quality Biosimilars. For Better Access to Vital Medicines.**

Would you like to join a fast moving and rapid growing biotech company? Everyone of us makes a difference!

We use the recruiter service by Constares. The vacancy is supervised by Constares consultants. For any questions, please contact Rebecca Schön:

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