

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 position limited to 2 years, to begin work as soon as possible:

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

### Your responsibilities:

- Planning, writing and compilation of regulatory documents for Formycon's biosimilar development programs with focus on CMC for drug substance development, site transfers and life cycle activities
- Review and approval of documents/plans/reports from CMOs/CROs and internal functional departments
- Support the coordination of regulatory activities for Formycon's Biosimilar development programs with involved stakeholders (e.g. internal functional departments, external CMOs/CROs, license partners)
- Support RA Managers of respective CMC team
- Participation in technical project teams
- Regulatory compliance check of documents and evaluation of change controls

### Your qualifications:

- Scientific background with master degree or PhD preferably in biology, biotechnology, pharmaceutical sciences, chemistry or equivalent
- First practical experience in compilation of CMC documentation for IMPD/IND, BLA/MAA for biotech products or 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](#)

A close-up, high-contrast photograph of a person's eyes, looking directly at the camera. The eyes are a striking blue-green color, and the image is cropped to focus on the eyes and upper eyelids.

**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:

**P: +49 89 1241 46 204**