

Formycon AG is one of the world's leading developers of biosimilars. With an experienced team comprised of more than 90 professionals, the company is able to span the entire value chain of biosimilar drug development, from laboratory analysis to clinical trials and all the way through to regulatory approval and market launch.

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:

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

Your responsibilities:

- Planning and preparation of documentation for the approval of biotechnology-derived medicinal products in USA and Europe with focus on CMC (e.g., Briefing Books, IND / IMPD, CTD Module 3, response to health authority questions)
- Coordination and execution of regulatory activities for our development programs with the involved departments (development, quality control and quality management) and in cooperation with our licensing partners
- Participation in project teams and contacts to external partners and contract manufacturers regarding regulatory activities
- Control, processing and release of the documentation of contract manufacturers as well as internal development reports
- Development and implementation of regulatory strategies and support for tech transfers of biotechnological drug substances
- Regulatory compliance checks and assessment of changes
- Ensuring compliance with relevant regulations and guidelines

Your qualifications:

- Science degree, preferably biology, biotechnology, pharmacy or chemistry or related field
- Requires 3-5 years of experience in the field of regulatory affairs in the US and Europe
- Practical experience in writing of CMC drug substance documents for BLA / MAA submissions
- Sound knowledge of the requirements for the development and production of biotechnology-derived active substances
- Preferably experience with tech transfer projects
- Ideally, knowledge of the EMA / FDA guidelines and requirements for the development of biosimilars
- Enthusiasm and creativity for the design of a biopharmaceutical company
- Safe German and very good English language skills
- Independent, careful, structured way of working

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](#)

Formycon AG uses the services of Constares GmbH in its recruitment process, which will screen all applications for this position. Should you have any questions about your application, please contact Mr. Gunnar Mayr at Constares GmbH at +49 89 1250 398 32.