Formycon AG is one of the world's leading developers of biosimilars. With an experienced team comprised of more than 100 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:

Regulatory Affairs Manager (CMC) - Drug Product Development (m/f/d)

Your responsibilities:

- Planning, writing and compilation of regulatory documents for Formycon`s biosimilar development programs with focus on CMC documentation for drug product development, site transfers, design control for combination products and lifecycle activities
- Coordination of regulatory activities for Formycon`s Biosimilar development programs with involved stakeholders (e.g. internal functional departments, external CMOs/CROs, license partners)
- Development and implementation of CMC regulatory strategies during product development and throughout lifecycle. Ensure that relevant regulatory requirements and guidelines are taken into account and implemented in the biosimilar development programs
- Participation in technical project teams and point of contact for external partners and CMOs/CROs for regulatory topics
- Review and approval of documents/plans/reports from CMOs/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
- Practical experience in compilation of CMC documentation for IMPD/IND, BLA/MAA required
- Ideally two or more years of experience in CMC RA area with focus on aseptically manufactured drug products
- First experience with design control process for combination products or medical devices would be of advantage
- Experience with biosimilars and knowledge of corresponding EMA/FDA guideline requirements would also be of advantage
- Ability to coordinate, prioritize and manage a variety of tasks and issues
- Team player, flexible and dedicated personality
- Fluent in English (German language a plus)

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 Coredi Recruiting. The vacancy is supervised by Coredi consultants. For any questions, please contact Mr. Gunnar Mayr:

T +49 89 1250 398 32

Formycon AG
Global Quality Biosimilars