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 Director Regulatory Affairs (m/f/d)

You will be responsible for defining and implementing regulatory strategies from preclinics up to registration. You will also be responsible for ensuring compliance with applicable regulations and will contribute to out-licensing activities. Your role is key for defining development paths for Formycon's development projects. In this position you reports directly to the Director of Regulatory Affairs and Quality Management.

Your responsibilities:

- Define RA strategy for Formycon's development projects with main focus on US and Europe and lead its implementation
- Ensure timely preparation of regulatory documents (e.g. Briefing Books, IMPD/IND; BLA/MAA)
- Guide cross-functional teams in defining the best strategy for each submission, their content and the contribution of each team member to their preparation
- Lead and coordinate submissions, such as: INDs/CTAs, Briefing Documents for Health Authorities, PIP/PSP, MAA/BLAs etc.
- Coordinate health authority interactions and support to prepare the team for meetings with FDA/EMA and other Regulatory Agencies
- Maintain knowledge of global competitive landscape, regulatory environment, and regulations.
- Manage regulatory CROs in charge of assigned work packages
- Contribute to the continuous improvement of internal processes, maximizing opportunities for improvement while ensuring compliance to applicable regulations
- Management responsibility for regulatory affairs team (>10 team members); develop, direct and coach direct reports
- Compilation and maintenance of project, budget and capacity plans

Your qualifications:

- Scientific background with master degree or PhD, preferably in biology, biotechnology, pharmaceutical sciences, chemistry or equivalent
- At least 10 years pharmaceutical industry experience, including minimum 6 years in regulatory affairs.
- Thorough knowledge of the drug development process with demonstrated experience in multiple development phases up to submission
- Strong experience in regulatory CMC for biologics is a must; experience in clinical strategy and/or biosimilar experience is of advantage
- Excellent written as well as presentation and communication skills in English
- Strong leadership, talent management and networking skills
- Entrepreneurial mindset
- 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:

P: +49 89 1241 46 204

Formycon AG
Global Quality Biosimilars