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

Regulatory Affairs Manager (Design Control) (m/f/d)

Your responsibilities:

- Planning, writing and compilation of design control documents for Formycon`s development programs with focus on drug-delivery combination products (e.g. prefilled syringes, auto injectors) including lifecycle activities
- Coordination of Design Control activities for Formycon`s development programs with involved stakeholders (e.g. internal functional departments, external CMOs/CROs, device supplier, license partners)
- Development and implementation of drug-device combination development strategies during product development and throughout lifecycle. Ensure that relevant regulatory requirements and guidelines are taken into account and implemented in the combination product development programs
- Review and approval of Design Control documents/risk-assessments/specifications/analytical protocols and reports from CMOs/CROs and internal functional departments
- Support compilation of Briefing documents and health authority interactions for the alignment of drug-delivery combination product development strategies
- Participation in technical project teams and point of contact for external partners and CMOs/CROs for combination product development topics
- Liaison with clinical department for design of human factor studies
- Contact partner for notified bodies for notified body assessment
- Regulatory compliance check of documents and evaluation of change controls

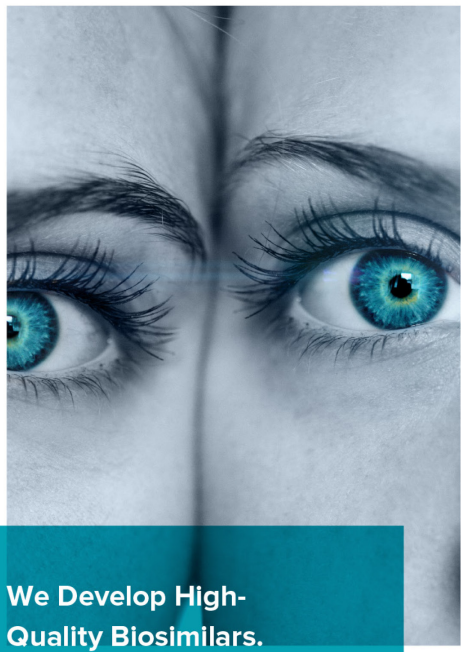
Your qualifications:

- Scientific background with bachelor or master degree preferably in biology, biotechnology, pharmaceutical sciences, chemistry or equivalent
- Minimum three years of experience in Medical Device Development area with focus on Design Control, Technical documentation and Risk Management for drug delivery systems
- Practical experience in compilation of Design Control/Technical documentation for drug delivery systems
- Experience with drug-device combination 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:

P: +49 89 1241 46 204

Formycon AG
Global Quality Biosimilars