

Formycon AG is one of the world's leading developers of biosimilars. With an experienced team comprised of more than 110 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:

Senior Manager Quality Management (m/f/d)

In this position you will be acting as a quality expert and consult your internal colleagues and external partners on all matters of quality. As such you interact with a variety of contract testing and manufacturing partners and help to ensure the quality requirements in challenging development projects of biosimilars.

Your responsibilities:

- QM representative for assigned biosimilar projects from early development till pre-commercialization
- Be a member of the project team and enforce compliance with internal and cGxP requirements at each single project step
- Review of external quality relevant documentation, e.g., validation, batch records, analytical methods
- Provide quality input and organize review and approval of project related changes, deviations, OOX and investigations
- Prepare briefings and data summaries e.g. product specification files
- Assure qualification of all suppliers among the projects
- Responsible for drafting, and concluding of Quality Agreements with third parties
- In perspective release of IMP batches for clinical supply
- Support continuous improvement of Formycon's QMS

Your qualifications:

- Degree (master, diploma, PhD) in pharmacy, chemical engineering, biotechnology, or a related field
- Minimum of 5 years' experience in the pharmaceutical quality assurance
- Very good knowledge of international GxP regulations
- Certified as a Qualified Person acc. to §15 German Drug Law desirable but not a must
- Experience in the field of biotechnological production of active ingredients and drug products
- Fluent in written and spoken English. Basic German knowledge is considered advantageous
- Very good team player, result oriented, persistent, well organized, proactive, problem solver and able to work independently
- 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 break new scientific ground with Formycon? Work together with dedicated scientists at the cutting edge of medical research!

We use the recruiter service by Coredi Recruiting. The vacancy is supervised by Coredi consultants. For any questions, please contact Mr. Gunnar Mayr:

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