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 candida for the following fulltime permanent position, to begin work as soon as possible:

Head of Quality Management – Analytical Laboratories (m/f/d)

As Head of Quality Management – Analytical Laboratories you will be responsible for ensuring the maintenance and continuous improvement of Formycon's GMP-based Quality Management System (QMS) with respect to our development and GMP QC laboratories.
In your new role you will lead a team of QM managers. You will be acting as a quality expert and consult your internal colleagues of the various operational departments on all matters of quality. Your reporting line is to the Associate Director QM.

Your responsibilities:

- Management and development of the QM team responsible for analytical lab activities
- Responsible for all internal quality processes as change control, deviations, training, review of analytical documents, internal audit, equipment qualification and validation of computerized systems
- Provide expert advice to Formycon's internal processes within relevant departments (e.g., Protein Analytics, Drug Product and IT) for quality related topics
- Support continuous improvement of our internal Quality Management System
- Write / review SOPs
- Define and generate key performance indicators (KPI) and metrics and keep oversight and control on performance and efficiency of processes
- Preparation of and lead in regulatory inspections and customer audits and ensure close follow-up of corresponding CAPA plans
- Training and further education of the laboratory team on quality and data integrity standards including occupational health and safety

Your qualifications:

- Degree (master, diploma, PhD) in pharmacy, chemical engineering, biotechnology, or a related field
- Minimum of 6 years' experience in pharmaceutical QA and compliance functions with focus on analytical development and QC activities
- Proven track record on data integrity requirements, equipment qualification and validation of computerized systems
- Experience in FDA inspections would be of benefit
- Very good knowledge of international GxP regulations
- Excellent staff leadership and communication skills
- Fluent in written and spoken English, good command of German
- Very good team player, result oriented, persistent, well organized, proactive, problem solver and able to work independently

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 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