Senior Quality Manager
based in Zug, Switzerland

About Bioeq

Bioeq AG is a Swiss joint venture between the Polpharma Biologics Group and the Strüngmann family's investment company. We license, develop and commercialize a biosimilar, which is a successor product of Lucentis® (ranibizumab), a successful branded biopharmaceutical. We are a young and dynamic company, supported by an international network of experts. Bioeq AG out-licenses its products to established international pharmaceutical companies who ensure local distribution in each territory.

About the role

You will be responsible to maintain and improve the Quality Management System to ensure quality, integrity and safety of the medicinal products and compliance with GDP and applicable GMP requirements. You will report to the Head of Quality Assurance. Your main activities will be:

- Maintain SOP system
- Maintain the internal audit and supplier audit programs and perform supplier, service provider and customer qualification
- Prepare Quality Agreements and maintain the related process
- Perform supplier and customer audits
- Maintain GxP compliant training system
- Perform batch record and APR / PQR review of CMOs and prepare overall PQR's
- Manage change control, deviations and CAPA's
- Support FVP in obtaining valid license for company operations
- Support notification of competent authority in terms of quality defects and falsified products
- Support proper decision / handling on the final disposition of returned, rejected, recalled or falsified products
- Support CSV and system operation activities

About you

You have a cooperative, self-motivated and pro-active mindset. You combine excellent planning and execution skills with the ability to work effectively in multidisciplinary teams. Furthermore, you possess the following qualifications:

- PhD or Master in Pharmacy, Chemistry or equivalent
- Proven track record of 8+ years in pharmaceutical industry
- 5+ years in Production, QC and/or QA
- Sound knowledge of GMP/GDP requirements
- Excellent knowledge of Quality Management
- Good understanding of drug substance / drug product development, manufacturing process, quality control, packaging and distribution
- Knowledge in biosimilars manufacturing and aseptically filling processes
- Ability to interpret and implement quality standards, pro-actively initiate and lead quality compliance activities and manage complex projects / tasks with competing priorities
- Ability to develop effective working processes with internal/external partners and cross-functional project teams
- Fluent in German and English

How to connect

If this unique opportunity resonates with your plans and aspirations, feel invited to apply with your CV in English and in .pdf format via email to office@bioeq.ch.