Quality Assurance Manager for Biological Drug Product

About Bioeq

Bioeq AG is a Swiss biopharmaceutical joint venture between Polpharma Biologics Group and Formycon and is based in Zug. We license, develop and commercialise 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 you

You have a cooperative, self-motivated and proactive 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 3+ years in pharmaceutical industry
- 2+ years in Production, QC and/or QA
- Sound knowledge of GMP/GDP requirements
- Excellent knowledge of Quality Management
- Good understanding of drug product manufacturing processes, 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

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 Senior Quality Assurance Manager DP.
Your main activities will be:

- Take care of all quality aspects of the CMO's for manufacturing, packaging and distribution of Bulk Drug Products and Finished Drug Products
- Maintain SOP system
- Maintain the internal audit and supplier audit programmes 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 licenses for company operations
- Support CSV and system operation activities

How to connect

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