Head Quality Management (Responsible Person FvP) part-/full-time based in Zug, Switzerland

About Bioeq

Bioeq AG is a Swiss biopharmaceutical joint venture between 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.

About the role

You will act as Responsible Person and be responsible for a GxP-compliant pharmaceutical QMS and for coordinating quality across our supply network to ensure safety, efficacy and quality of the products delivered to our global partners. In this exciting role you will manage three main areas:

- **Quality management of supply network**
  - Qualify, evaluate and supervise suppliers, logistics service providers and CMOs
  - Conduct audits and support inspections at suppliers, logistics service providers and CMOs
  - Establish appropriate Quality Agreements
  - Establish appropriate Quality Oversight principles for the contracted services
  - Host customer audits
  - Review of quality related documentation issued by CMOs
  - Assess and coordinate release activities with release sites
  - Ensure quality and regulatory compliance to the registered dossier, including and not limited to change management.

- **Quality Management System**
  - Maintain Quality Management Systems for the Bioeq AG organisation and ensure compliance with the regulatory applicable local and global requirements
  - Prepare, review and maintain SOPs
  - Manage deviations, CAPAs, changes and complaints
  - Maintain and improve Bioeq's quality training system
  - Validate systems and processes
  - Perform internal audits

- **Coordination with authorities**
  - Ensure that the required HA licenses and GxP certifications are in place and up to date
  - Host inspections by authorities
  - Communicate with authorities within the scope of a Responsible Person

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 international matrix organizations. Furthermore, you possess the following qualifications:

- University diploma / state examination in pharmacy or other natural sciences

- Proven track record of 5+ years in pharmaceutical industry internationally with at least 4 years GMP/GDP experience in a quality function, preferably as Responsible Person
- Sound knowledge of GMP/GDP, quality system requirements, as well as biopharmaceutical, Swiss and international (EU, US) pharmaceutical regulations
- Ideally trained as auditor and experience in supplier and CMO oversight and audits
- Fluent in both English and German

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 jobs@bioeq.ch.