Technical Regulatory Affairs Manager
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 Technical Regulatory Affairs Manager and maintain the Technical Regulatory System and its compliance with applicable regulatory requirements in the different countries and also be responsible for the medical device compliance activites. Your main actitivities will be:

- **Maintain the approved dossiers over the lifecycle of the products**
  - Ensure that Technical Regulatory procedures and records with respect to CMC / Quality are in compliance with applicable regulations and standards
  - Prepare on time CMC part of BLA/MAA registration documentation for regulatory submissions/variations as well as for other countries where the dossier needs to be updated
  - Ensure that regulatory variations are accurate and verifiable against source documents to confirm compliance and traceability

- **Prepare submissions for new markets**
  - Adapt existing dossiers and support implementation of new dossier parts needed to get approval in new markets
  - Participate in expert discussions with different authorities prior approval and support answering questions that come up during approval review

- **Maintain the Quality System for Regulatory Activities**
  - Collaborate closely with external service providers on Technical Regulatory Affairs aspects
  - Support Senior Management and Line Manager in all Technical Regulatory Affairs aspects
  - Collaborate with Regulatory Affairs functions within and outside the company
  - Interact with Health Authorities on Technical Regulatory Affairs aspects of the company

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 7+ years in pharmaceutical industry internationally with at least 5 years GMP/GDP experience in a regulatory function, preferably as Technical Regulatory Affairs Manager

- Sound knowledge of EU, US and CH GMP/GDP regulations, in quality system requirements, as well as from biopharmaceuticals
- Ideally you have already submitted new applications and maintained dossiers over their lifecycle
- Fluent in 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 via email to jobs@bioeq.ch.