Regulatory Affairs Manager

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 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 activities. Your main activities will be:

- **Maintain the approved dossiers of the lifecycle of the products**
  - Ensure that Regulatory procedures and records with respect to CMC / Quality are in compliance with applicable regulations and standards
  - Prepare administrative documentation on time and Module 1 documentation for regulatory submissions / variations as well as provides support to CMC writing for initial MA submission in various regions. Ensure that regulatory variations are accurate and verifiable against source documents to confirm compliance and traceability
- **Prepare submissions for new markets**
  - Participate in expert discussions with different stakeholders' prior approval and support by answering questions during the approval process
- **Maintain the Quality System for Regulatory Activities**
  - Collaborate closely with external service providers (e.g. publisher or CMC writing) on Regulatory Affairs aspects
  - Support Senior Management and Line Manager in all Regulatory Affairs aspects
  - Collaborate with Regulatory Affairs functions within and outside of the company
  - Interact with Health Authorities on Regulatory Affairs aspects of the company
  - Manage Change control system and coordinate information to all relevant stakeholders on time
  - Assure post marketing surveillance regarding pharmaceutical legislation and guidance in Switzerland

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 organisations. Furthermore, you possess the following qualifications:

- University degree / state examination in pharmacy or other natural sciences
- Proven track record of 7+ years in the pharmaceutical industry in Life Cycle Management internationally with at least 5 years of GMP/GDP experience in a regulatory function, preferably as Regulatory Affairs Manager
- Experience of working in different regulatory regions
- Sound knowledge of EU, US and CH GMP/GDP regulations, in quality system requirements, as well as from biopharmaceuticals
- Good knowledge of eCTD structure and its compilation
- 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 full dossier in English and in pdf format via email to office@bioeq.ch