

Acino is a Swiss pharmaceutical company, leader in advanced drug delivery technologies. We have a clear focus on selected emerging markets in the Middle East, Africa, the CIS Region, and Latin America, and we operate in some of the most dynamic countries of the world. We value courage, commitment, trust, and empathy and provide an environment that supports initiative and effort. We are proud to be action-oriented and open-minded, with a strong focus on quality and product availability, even in remote and hard to reach areas of the world.

We are currently looking for a

Regulatory Affairs Manager (f/m) 100%

This position is based in Zürich / Oerlikon.

Your main responsibilities include:

- Responsible for implementing the global regulatory needs during the development and lifecycle of the assigned products
- Implementing the global regulatory needs during the development and lifecycle of the assigned products
- Advising project teams in registration questions with focus on regulatory strategy, but also in terms of e.g. preclinical and clinical aspects in collaboration with the specialists of the line functions (Medical Affairs, Marketing, Clinical Development, Commercial Operations, Supply Chain)
- Interact with regulatory agencies and is the regulatory representative for Switzerland and EU region; further countries may be applicable dependent on the product

Your profile:

- Minimum educational requirement is a Master's Degree in Pharmacy, Chemistry, Biology or another life science
- More than 5 years of experience in pharmaceutical industry, preferably in international regulatory affairs
- Proficiency in European legislation and ideally also CH, FDA regulations, policies, procedures and respective guidelines
- Hands-on experience in evaluation of change control requests
- Experience with creation, review and finalization of MA applications as well as variation packages for CH
- Excellent planning and organizational skills and ability to drive the regulatory process with a sense of urgency, both internally through multi-disciplinary teams and externally through the effective use of third parties as well as effective communication and negotiation with regulatory authorities
- Fluent in writing and negotiation in German and English. Know-how in further languages is of advantage
- Computer literacy (MS-Office-Tools), good understanding of database and document management systems (docuBridge)

This is the opportunity to join a very dynamic organization, where decisions are taken fast and where you can actively participate in shaping our future. If this sounds exciting, we would love to hear more about you! Please send us your complete application to - **preferably via e-mail into one PDF document** - to Ms. Emmanuelle Leblanc.

Emmanuelle Leblanc
HR Specialist
HR.International@acino.swiss

We are looking forward to the opportunity to get to know you.
Only direct applications are considered.