



*AOP Health is the European pioneer for integrated therapies for rare diseases and in critical care. To enhance our team in Vienna we are looking for a:*

## Regulatory Affairs Manager (f/m/d)

### Professional Skills

- University degree in Natural Science
- 3-5 years Regulatory Affairs experience in the pharmaceutical industry
- In-depth knowledge of international regulatory requirements
- Experience in Regulatory Affairs CMC
- Ability to strategically plan, prioritise and manage multiple projects
- Attention to details and ability to deliver high quality regulatory documentation
- Strong communication skills to liaise with internal and external partners with different cultural backgrounds
- Full proficiency in MS Office, knowledge of Sharepoint and an eCTD publishing tool is a plus
- Fluent in English and German

*As part of our Regulatory Affairs team you will play a key role in the submission of new regulatory projects and in the life cycle management of existing licences ((EU and non-EU scope).*

### Ready for an ambitious job?

- You are responsible for the preparation and compilation of registration dossiers according to country specific requirements in collaboration with other functions.
- You coordinate, review and proof-read responses to questions from authorities.
- You evaluate changes for regulatory impact and filing requirements.

### Able to align?

- You act as regulatory contact person for authorities, external partners and in-house functions.
- You provide regulatory guidance and strategy to Project Teams involved with the development of new products.
- You offer CMC regulatory expertise for proposed changes within life cycle management and during pharmaceutical development activities.
- You are a team player and like to work cross-functionally and with external partners.

### Looking for an agile environment?

- You prefer working with a high degree of independence and responsibility for assigned projects.
- You have a pro-active attitude, the ability to develop new concepts and a creative approach to problem-solving.
- You enjoy working in a growing international company introducing solutions for rare diseases to new markets.

*The gross monthly salary provided for this function is a minimum of € 4.000.- based on full-time employment. Any potential overpayment depends on professional experience and qualifications.*

**Take this AOPPORTUNITY and [apply now.](#)**

### Your contact

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**MAKE** IT HAPPEN