



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:

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

Professional Skills

- University degree in Natural Science
- 3-5-year Regulatory Affairs experience in the pharmaceutical industry
- In-depth knowledge of international regulatory requirements
- 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

Like to take accountability?

- You will play a key role in the submission management of new regulatory projects and in the life cycle management of existing licences (EU and non-EU scope)
- You provide regulatory guidance and strategy to Project Teams involved with the development of new products
- As Senior RA Manager you are responsible for a group of RA Managers and you provide leadership, guidance and mentoring

Able to align?

- You act as regulatory contact person for authorities, external partners and in-house functions
- You offer CMC regulatory experience 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 high-performing and international company environment

The gross monthly salary provided for this function is a minimum of € 3.500.- based on full-time employment. Any potential overpayment depends on professional experience and qualifications.

Take this AOPPORTUNITY and **apply now.**

MAKE IT HAPPEN

or contact

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