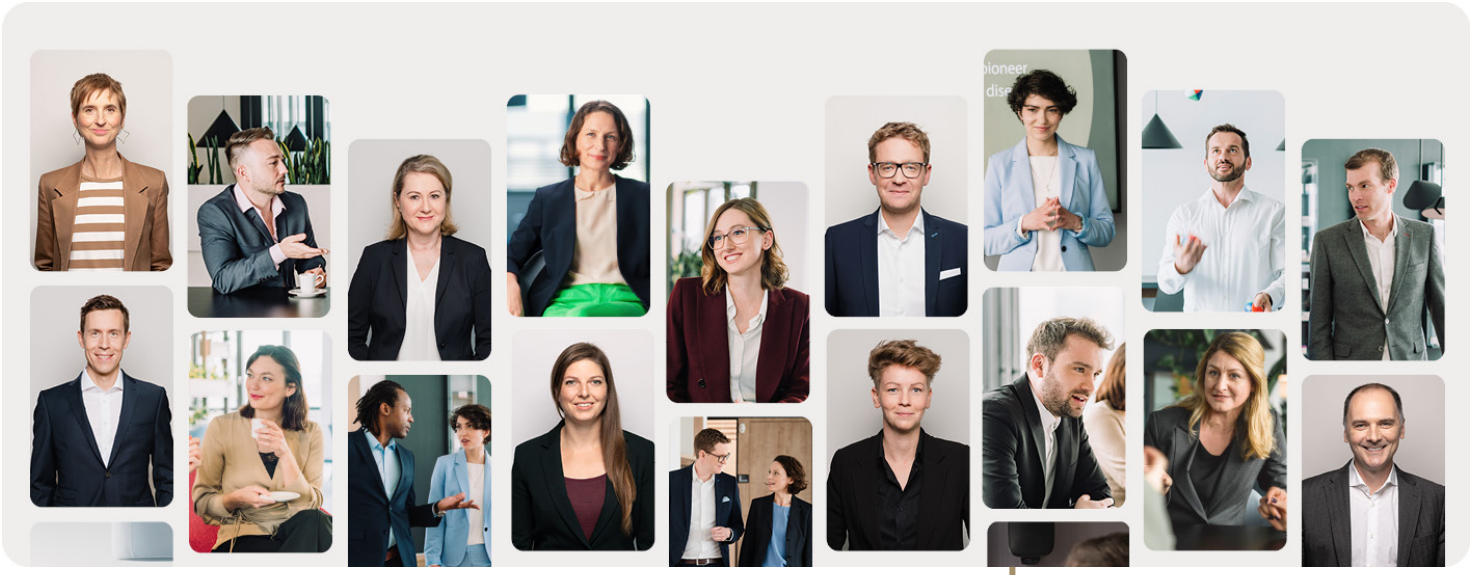
AOP Health is the European pioneer for integrated therapies for rare diseases and in critical care. To enhance our team in Vienna we are looking for a:

Regulatory Affairs Manager (f/m/d)

1190 Vienna | Full-time employee | Start: as of now |



About the Role: In this role you are responsible for the development and implementation of regulatory strategies to ensure successful registrations and product launches for AOP Health products.

What Your Day To Day Will Look Like

- You will be responsible for preparing and compiling registration dossiers according to country specific requirements in collaboration with other functions.
- Compile high quality eCTD sequences as required in the eCTD publishing tool
- Coordinate, review and proof-read responses to questions from authorities
- Evaluate changes for regulatory impact and filing requirements
- Ensure regulatory compliance by maintaining relevant data and documents in the Regulatory Database and Document Management System
- You report to stakeholders, including communication of approvals, worldwide marketing authorization status and other relevant information from Regulatory Databases
- You will play a key role in the submission management of new regulatory projects and in the life cycle management of existing licenses (EU and non-EU scope)
- Provide regulatory guidance and strategy to project teams involved in new product development
- Develop global regulatory strategy for assigned product(s) including submission strategy, timelines, recommendations regarding expansion plans and country requirements etc.
- Manage payments for regulatory procedures and annual fees

Main Benefits

- Bonus
- Homeoffice
- Flexible working hours
- Initial and continuing education
- Canteen
- Good transport connection
- Employee events
- Meal allowance
- Company doctor
- Parking spot

Your Contact

- Act as regulatory contact person for authorities, external partners and in-house functions
- Provide regulatory advice on proposed changes to life cycle management and pharmaceutical development activities
- Manage projects within the department as well as interdepartmental projects

Your Qualifications and Experience

- University degree in Natural Science
- At least 3-year RA experience in the pharmaceutical industry in an international environment
- 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 and submissions
- Solution-oriented way of working
- 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, any other language is a plus

Our offer

- A position with personal responsibility and space for creativity
- Open corporate culture with the opportunity to bring in your own ideas
- Highly motivated, agile, and international team
- Great opportunities for personal and professional development
- Attractive work environment with excellent career opportunities and flat hierarchies
- Competitive salary package plus bonus and various benefits
- Gross monthly salary provided for this function is a minimum of EUR 3.800.- based on full-time employment. Any potential overpayment depends on professional experience and qualifications.

If you would like to work as a team player in an international environment and can identify with our values "Agile, Ambitious, Aligned, Accountable and Appreciative", then: Take this CHANCE!

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Further information on our website:
aop-health.com