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 Manager Global Regulatory Affairs Strategy (f/m/d)

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

In this role, you will lead global regulatory strategies for biologics and small molecules across all development stages. You'll define scientifically sound, commercially aligned pathways to ensure timely submissions and market access, while serving as the key regulatory contact for assigned regions, products, and projects.

What Your Day To Day Will Look Like

- Act as Regulatory Lead for assigned EU and non-EU projects, coordinating all regulatory activities and strategies.
- Prepare and compile regulatory dossiers for marketing authorization applications (MAA) and lifecycle submissions.
- Submit dossiers via electronic portals and manage interactions with health authorities, including responding to queries.
- Prepare and review submission documentation, including Modules 1–5, ensuring high-quality, timely delivery.
- Serve as the main regulatory contact for authorities, external partners, and internal stakeholders.
- Contribute to the creation and implementation of global regulatory strategies and project management plans.
- Participate in cross-functional teams (e.g., Program Teams, Technical Program Teams, Brand Teams), ensuring alignment of regulatory input.
- Support budget planning and documentation efforts related to assigned regulatory projects.
- Oversee the creation and review of product-related artwork from a regulatory perspective.
- Consistently demonstrate leadership in ambiguous or first-time situations across matrixed environments.

Main Benefits

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

Your Contact

Your Qualifications and Experience

- Advanced degree in life sciences, pharmacy, or medicine (e.g., MSc, PhD, PharmD, MD).
- Several years of experience in regulatory affairs, ideally in global roles and across lifecycle stages.
- Strong understanding of EU and non-EU regulatory environments and submission formats (e.g., eCTD)
- In-depth knowledge of ICH guidelines and the broader global regulatory landscape.
- Excellent command of English, both written and spoken.
- Demonstrated ability to collaborate cross-functionally and influence stakeholders in matrix teams.
- Strong organizational and communication skills, especially with external authorities and partners.
- Proactive, solution-oriented mindset with the ability to manage ambiguity and dynamic priorities.

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, various benefits
- Gross annual salary for this function is a minimum of EUR 90.000.- based on full-time employment (38.5 hours/week). 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!

Julia Friedl
Talent Acquisition Manager

Further information on our website:
aop-health.com