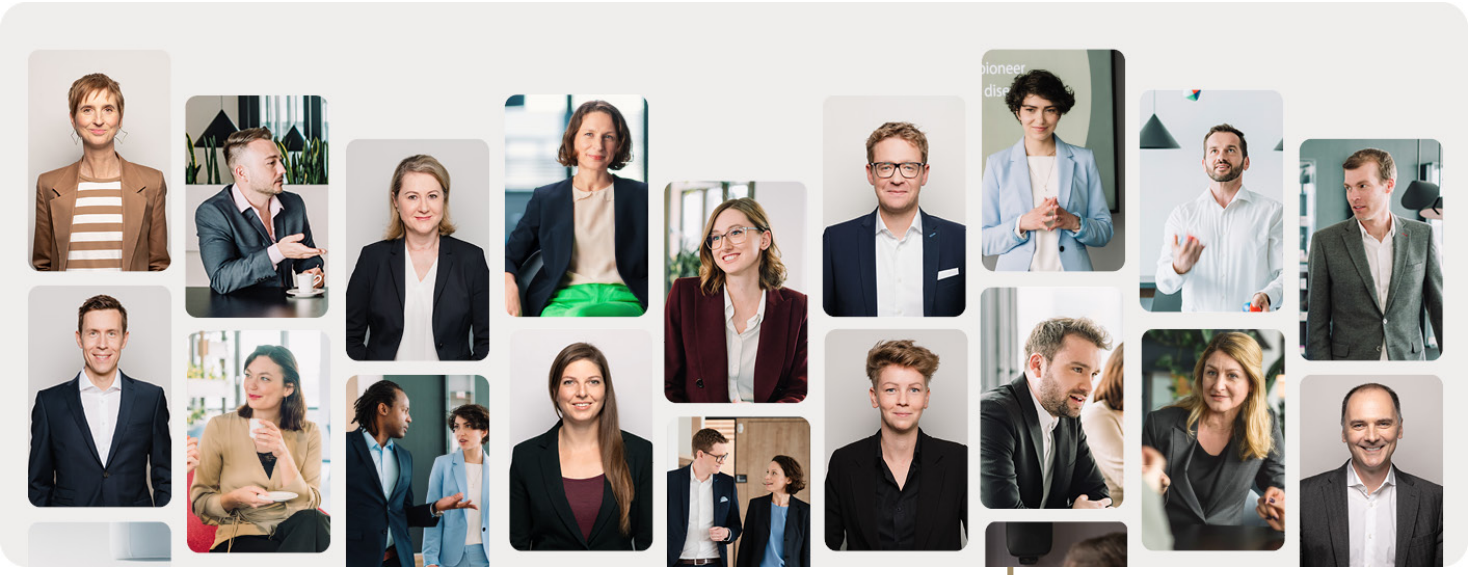
AOP Health is the European pioneer for integrated therapies for rare diseases and in critical care. To enhance our team in Vienna we are looking for a:

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

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



In this role, you will lead the development and execution of global regulatory strategies for a diverse portfolio of biologics and small molecules, spanning early development, registration, and lifecycle management. You will define regulatory pathways that are both scientifically sound and commercially strategic, ensuring timely submissions and maximizing product access across key international markets.

What Your Day To Day Will Look Like

- Lead global regulatory strategies for development and marketed products across key therapeutic areas (e.g., rare diseases, oncology, immunology).
- Serve as Global Regulatory Lead on cross-functional teams, aligning regulatory input with corporate objectives.
- Represent AOP Health in strategic interactions with global health authorities (e.g., FDA, EMA, PMDA, MHRA).
- Oversee timely submission of key regulatory dossiers, including MAA, NDA, BLA, orphan drug and expedited pathways, and pediatric plans.
- Ensure globally aligned regulatory content by collaborating with Regulatory Operations, CMC, Clinical, Preclinical, and regional teams.
- Assess regulatory risks and opportunities, supporting strategic planning and mitigation.
- Monitor global regulatory trends and competitor activity to inform proactive strategies.
- Support regulatory due diligence for pipeline opportunities and partnerships.
- Mentor junior team members and foster internal knowledge-sharing.

Main Benefits

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

Your Qualifications and Experience

- Advanced degree (MSc, PharmD, PhD, MD) in life sciences, pharmacy, or medicine.
- 12+ years in regulatory affairs, including 5+ years in global strategy roles.
- Proven success with major global submissions and approvals in both large and small companies.
- Strong knowledge of ICH, GxP, and key regulatory frameworks (e.g., FDA, EMA, PMDA, MHRA) including orphan drug regulatory incentives and relevant procedures.
- Experience with biologics, advanced therapies, medical devices, or novel modalities is a plus.
- Effective leader with strong cross-functional collaboration and influencing skills.
- Clear and confident communicator, experienced in external representation.
- Comfortable working in a hybrid setting that blends structure with agility.

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, company car and various benefits
- Gross annual salary for this function is a minimum of EUR 100.000.- 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!

Your Contact

Julia Friedl
Talent Acquisition Manager

Further information on our website:
aop-health.com