



OrphaCare is a subsidiary of AOP Health that specializes in medical devices and patient support solutions for treating rare and complex diseases.

To enhance our team in Vienna we are looking for a:

## Director Quality Assurance & Regulatory Affairs (OrphaCare)

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



***We are looking for a Director, Quality Assurance & Regulatory Affairs to lead OrphaCare global quality, regulatory, and compliance organization. This executive leadership role is responsible for overseeing the company's Quality Management System, Quality Assurance, Regulatory Affairs, and compliance strategy across the full product lifecycle. Reporting directly to the Managing Director, you will ensure compliance with global regulatory requirements, support product development and commercialisation, drive inspection readiness, and provide strategic leadership for quality, regulatory, product safety, and compliance activities.***

### **What Your Day To Day Will Look Like**

- Develop and execute the global Quality & Regulatory Affairs strategy aligned with business objectives and growth plans.
- Serve as a trusted advisor to executive leadership on quality, regulatory, compliance, and product safety matters.
- Lead, mentor, and develop a high-performing global QARA organization.
- Ensure the effectiveness and continuous improvement of the global Quality Management System in compliance with ISO 13485 and applicable regulations.
- Drive regulatory strategies supporting product development, market access, lifecycle management, and international expansion.
- Maintain organizational inspection readiness and lead interactions with regulatory authorities, Notified Bodies, and external auditors.
- Provide Quality and Regulatory leadership throughout product development, clinical activities, and post-market surveillance processes.
- Oversee quality and compliance across manufacturing, supplier, and distribution activities to ensure regulatory adherence and operational excellence.

- Manage quality and regulatory budgets, external partners, and resource planning to support strategic objectives.
- Foster a culture of quality, patient safety, continuous improvement, and cross-functional collaboration across the organization.

## Your Qualifications And Experience

- Bachelor's degree or higher in Engineering, Life Sciences, or a related discipline.
- 15+ years of progressive leadership experience in Quality Assurance and Regulatory Affairs within the medical device industry.
- Demonstrated experience with Class III and/or Active Implantable Medical Devices (AIMD).
- Expert knowledge of global medical device regulations and standards, including ISO 13485, FDA QMSR (21 CFR Part 820), and EU MDR.
- Proven track record leading regulatory inspections, Notified Body audits, certifications, and compliance remediation activities.
- Strong experience in developing and improving Quality Management Systems and driving organisational quality transformation initiatives.
- Strategic leadership capabilities with experience leading global, cross-functional teams and managing organisational change.
- Strong business acumen, budget management, and stakeholder engagement skills.
- Excellent communication and influencing skills with the ability to engage effectively at executive level and with external authorities.
- Fluent English with a strong commitment to quality, compliance, integrity, and patient safety.

## Our offer

- An open corporate culture with the opportunity to contribute your own ideas
- Working independently in a collegial and committed team
- Modern working environment with good public transport connections (U4 - Heiligenstadt)
- Flexible working hours (flexitime/time-out days), bonus scheme, additional benefits and employee events
- Structured onboarding and support through a buddy system
- Due to legal requirements, we are obliged to disclose the collective agreement minimum salary, which is EUR 65.660,- gross per year, based on full-time employment. However, our actual remuneration packages are market-oriented and aligned with your qualifications and professional experience.

*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 and*

### Main Benefits



Bonus



Homeoffice



Employee mobile phone



Flexible working hours



Laptop



Initial and continuing education



Canteen



Good transport connection



Employee events



Meal allowance



Company doctor



Parking spot



Healthmeasures



Employee discount

## Your Contact



**Larisa Barkowski**

Talent Acquisition Lead

*Further information on our website:*

[aop-health.com](http://aop-health.com)