

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 we are looking for a:

Senior Quality Manager (Orpha Care)- fixed-term until 31.12.2028

1190 Wien | Vollzeit | Start: as of now |



We are looking for an experienced and motivated Senior Quality Manager to join our OrphaCare QARA team. In this role, you will lead the development and maintenance of our Quality Management System (QMS) for Class III active implantable medical devices and play a key role in advancing our eQMS implementation and quality harmonization initiatives.

What Your Day To Day Will Look Like

- Develop, maintain, and continuously improve the Quality Management System in accordance with ISO 13485:2016 and applicable EU Medical Device Regulation (MDR) and FDA QMSR requirements.
- Identify QMS gaps and drive the development, revision, and implementation of procedures, work instructions, templates, and records.
- Harmonize quality processes and documentation across company sites.
- Collaborate closely with QA, RA, and technical teams to establish and maintain compliant quality processes covering design controls, risk management, supplier management, production controls, validation, complaints, and post-market surveillance.
- Support and lead key activities related to the implementation and deployment of the electronic Quality Management System (eQMS).
- Define user requirements, workflows, document structures, metadata, access permissions, and reporting requirements for the eQMS.
- Coordinate validation activities, user training, and go-live support to ensure the eQMS remains in a validated state.

Your Qualifications And Experience

- Degree in scientific, engineering or quality-related discipline
- 7-10 years of experience in medical device quality management.
- Practical knowledge of ISO 13485, EU MDR and FDA requirements, and quality management processes.
- Experience in developing procedures, implementing QMS continual improvements, and managing quality

documentation.

- Hands-on experience with eQMS implementation, administration, validation, and training.
- Experience with audits, CAPA, change control, and management review processes.
- Strong organizational skills, attention to detail, and the ability to work effectively across functions.
- Experience with Class III or implantable medical devices is considered a plus
- Fluent English; German is an advantage.

Our offer

- Open corporate culture with the opportunity to bring in your own ideas
- 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 annual salary provided for this function is a minimum of EUR 49.840,- based on full-time employment (38,5h/week). Any potential overpayment depends on professional experience and qualifications.

By submitting your application, you accept [AOP's Data & Privacy Policy](#).

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



Angelika Drabek
Manager Talent Acquisition

Further information on our website:
aop-health.com