PULMOTREE

Director Quality Management & Regulatory Affairs (m/f/d)

Location: München, *Maxvorstadt*

The Director Quality Management & Regulatory Affairs provides quality management and regulatory affairs leadership across the business within a highly regulated medical devices and combination product environment. The Director QM & RA will be responsible to develop and maintain the Pulmotree Medical Quality Management System according to the ISO 13485:2016 standards / FDA / GMP requirements and for all regulatory submissions to the relevant authorities.

Your Background

- A Diploma or Master degree in a relevant subject and/or suitable experience in a Quality and Regulatory role
- Excellent knowledge of ISO 13485:2016, MDR, FDA requirements, with experience supporting regulatory submissions
- Extensive knowledge of combination product requirements to support i.e. (Abbreviated) New Drug Applications
- Experienced in risk management according to ISO 14971
- Proven track record of preparing and managing successful quality audits (internal/external) and inspections
- Very good communication skills both in German and English language

CONTACT

Please send your application to **jobs@pulmotree.com** or visit our homepage for further information.

Pulmotree Medical GmbH // Steinheilstr. 3A // 80333 München

Registergericht: Amtsgericht München HRB 241170 // Geschäftsführer: Ulf Krüger

www.pulmotree.com