Breathe in. Breathe out. Think forward.

Pulmotree is a young, dynamic life sciences start-up based in Munich, Germany. Driven by new ideas and with many years of experience, we are forward thinking in patient treatments.

Regulatory Affairs Manager (m/f/d)

Location: München, Maxvorstadt

The Regulatory Affairs managers provides regulatory affairs leadership across the business within a highly regulated medical devices and combination product environment. This role will be particularly responsible for:

- Implement and maintain regulatory affairs policies and procedures to ensure regulatory compliance
- Provide regulatory guidance to the development teams
- Preparation and submission of new products i.e. 510(k) or in declaring CE conformity
- Monitoring regulations, guidelines, and standards

Your Background

- A Diploma or Master degree in a relevant subject and/or suitable experience in a regulatory role
- Excellent knowledge of MDR, FDA requirements, with experience in supporting regulatory submissions
- Extensive knowledge of combination product requirements to support i.e. New Drug Applications (NDA)
- Regulatory requirements for medical devices, medical software, and combination products
- 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.

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www.pulmotree.com