Regulatory Affairs Manager at the Institute for AI in Medicine, UME

Job Description

As a Regulatory Affairs Manager, you ensure compliance with all regulatory requirements for our medical devices for market access. You will work closely with various departments to ensure compliance and approval of our products.

Main Tasks

- Development and implementation of regulatory strategies for medical device development
- Preparation and submission of approval applications to authorities (e.g., BfArM, FDA, EMA)
- Establishment of processes
    - Implementation of a QM system according to ISO 13485
    - Risk assessments according to ISO 14971
    - Software lifecycle processes according to IEC 62304
- Development of a remuneration strategy
- Post-Market Surveillance
- Interdisciplinary collaboration with research and development, quality management, clinical departments, and external partners
- Monitoring changes in legislation and adaptation of internal processes

Qualifications

- Completed degree in a relevant field (e.g., Medical Informatics, Natural Sciences, Psychology, Engineering, Pharmacy)
- PhD preferred
- Ideally experience in Regulatory Affairs for medical devices
- Ideally experience with CE marking and FDA 510(k) submissions
- Excellent communication skills in German and English
- Strong analytical skills
- Goal-oriented with pragmatic solutions

Our benefits

- An attractive position in an innovative environment
- Professional development opportunities
- Attractive salary and comprehensive benefits
- A collegial and dynamic team
- Preferred location of the institute in the heart of the vibrant and trendy Essen-Rüttenscheid district
- Startup feeling with espresso machine, foosball table, and more