Regulatory Affairs Leader (m/f/d)

Setting

At midge, we're reimagining the way healthcare systems work. You'll have the chance to be part of that change within a diverse and fast-growing team. We are creating the exciting opportunity for you to leave your footprint.

midge medical is developing diagnostic devices based on blood and other body fluids that are so easy to operate that they can be used by consumers as well as by professionals. The complete digitization of the testing procedure is at the core of our vision. You can contribute to our team as Regulatory Affairs Leader and be at the center of all regulatory activities.

As Regulatory Affairs Leader, you will

work closely with the technology team within the quality organization to support our fast innovation product development process. As the Regulatory Affairs Leader you are responsible for developing regulatory plans with adequate level of complexity. Ensures regulatory compliance and optimization of quality system procedures relating to the regulatory requirements that affect Midge Medical. You will interact with governmental regulatory agencies and other third-party accrediting bodies.

- Provides regulatory support for diagnostic product development and commercial diagnostic products
- Develops regulatory strategies for product development and modification to achieve clearance/approval in Germany, EU and internationally
- Researches scientific and regulatory information in order to write, edit, and review documents
- Compiles and publishes all material required for submissions, license renewals, and annual registrations
- Works with governmental regulatory agencies and other third-party accrediting bodies
- Maintains approvals/licenses/authorizations for existing marketing authorizations
- Ensures accuracy of German/EU and international registration and device listing
- Provides recommendations on labelling, manufacturing, and analytical and clinical study plans for regulatory compliance
- Reviews validation reports for regulatory submission soundness
- Assesses product, manufacturing and labelling changes for regulatory reporting impact and compliance to regulations
- Proven ability to work independently to meet rigorous deadlines without a rigidly defined process in place
- Reviews advertising and promotion as required to ensure compliance with product claims
- Develops internal procedures and tools
- Conducts informational or training sessions for stakeholders
- Carries out duties in compliance with established business policies
- Demonstrates commitment to the development, implementation and effectiveness of Midge's Quality Management System per ISO, FDA, Health Canada, and other regulatory agencies

- Optimization of the Regulatory processes within the quality system to suit a rapidly growing company
- Conflicting departmental priorities and obstacles to change
- Ensuring compliance while meeting business objectives
- Responsible for exhibiting professional behavior with both internal/external business associates that reflects positively on the company and is consistent with the company's policies and practices
- Performs other duties and projects as assigned

Must-Have Assets are

- bachelor's degree or have completed a vocational training course and further training with additional professional experience
- 5+ years' professional experience in quality management or process management in the medical engineering or pharmaceuticals environment
- You can demonstrate very good knowledge of standards (ISO13485, ISO14971) and legal requirements (such as the German MPG, the EU MDR/IVDR), in particular concerning the qualification and classification of products
- Process oriented, logical, analytical, meticulous and highly organized
- Code of Federal Regulations 820, Medical Device Single Audit Program and eventually EN ISO 10993 as a plus

Preferred

- master's degree in medicine, medical engineering, (technical) communication, law, science, or a comparable discipline
- Other country medical device regulations such as the Canadian MDR or the US FDA
- 3+ years in an IVD or medical device manufacturing environment
- Driven individual with a history of developing collaborative, cross-functional solutions
- Adaptable and willing to take on multiple new tasks and responsibilities
- Experience working as part of teams following Agile Scrum methodology
- Experience implementing a compliant supply chain
- Green belt certification or Lean experience
- Experienced in the use of ERP software applications like SAP S4/Hana, Jira
- Travel required +/- 30%

Place of work
Berlin, Germany

When can you start?
As soon as we have agreed that we are a match!