

We are hiring!

Oncobit is a MedTech spin-off from the University of Zurich, developing novel cancer monitoring solutions. Our products are developed with world-leading scientists and physicians to enable personalized cancer care. As we have ISO certified our quality management system and CE-marked our first product, we are looking to hire a:

Quality and Regulatory Affairs Manager (100%)

as of November 1st, 2023, or as soon as possible.

Your key responsibilities

- You are responsible for Oncobit's quality management system and regulatory activities and serve as the first internal and external contact point
- You ensure the continuous improvement of our quality management system
- You contribute to the technical documentation and organize and control all activities necessary to secure regulatory approval of our products including clinical studies
- You are responsible for the organization of management reviews and (internal) audits
- You ensure the correct labelling and tracking of our products and handle support and complaint inquiries

Your profile

- MSc or PhD in biology or a related field
- Good understanding of relevant regulations and guidelines, particularly ISO13485, ISO15189 and EU 2017/746, IVDR (experience with ISO14971, IEC 62304, IEC82304 and IEC62366 is a plus)
- At least 2 years of experience with in vitro diagnostics, particularly in compiling technical documentation
- At least 2 years of experience in quality management
- Excellent written and spoken English and ideally German skills (other language skills are an additional asset)
- Very high work ethic

Soft skills

- You are committed to continuously implementing our quality management system with the necessary empathy for colleagues, customers, and partners
- You are a team player and have an entrepreneurial and pragmatic mindset
- You are diligent, precise, and reliable with excellent organizational skills
- And above all: you are enthusiastic about our mission to enable personalized cancer care!

Are you interested in converting the latest scientific findings into improved diagnostics for cancer patients? We are looking forward to hearing from you! Please send your CV and motivation letter to claudia.scheckel@oncobit.com.

www.oncobit.com

