

Quality and Regulatory Affairs Manager (100%)

 **Schlieren (Zurich)**

Join us in advancing precision oncology

Oncobit develops CE-IVDR-certified molecular diagnostics for precision oncology. As we continue to expand our product portfolio and clinical evidence, we are looking for an experienced Quality & Regulatory Affairs Manager to strengthen our team in Schlieren.

What you'll do

- Maintain and continuously improve our ISO 13485 Quality Management System
- Act as Risk Manager and lead risk management activities according to ISO 14971
- Prepare and maintain IVDR technical documentation throughout the product lifecycle (including software and assays)
- Lead the regulatory strategy for clinical performance studies and contribute to Oncobit's performance evaluation strategy under the IVDR
- Serve as the primary contact for regulatory authorities and Notified Bodies, including audit preparation and follow-up
- Lead internal audits, CAPAs, management reviews and post-market activities

What you bring

- MSc or PhD in Life Sciences or Computer Sciences or a related field
- Minimum 3 years of experience in Regulatory Affairs and/or Quality Management for medical devices (ideally for IVD software and assays)
- Strong knowledge of EU IVDR (2017/746), ISO 13485 and ISO 14971
- Experience communicating with and supporting audits by a Notified Body
- You are a team player who works in a structured, precise and reliable manner, with an entrepreneurial and pragmatic approach
- Excellent written and spoken English (German is an advantage)

What we offer

- A key role in bringing innovative molecular diagnostics into clinical routine
- A collaborative, interdisciplinary team with short decision paths
- High ownership and the opportunity to shape innovative IVDR-certified diagnostics

Apply now

We'd love to hear from you. Send your CV and motivation letter to:
claudia.scheckel@oncobit.com

www.oncobit.com

