ONCOLAB
Diagnostics GmbH solutions for personalized medicine

MANAGER PRODUCT QUALITY & REGULATORY AFFAIRS (f/m)

We are a small but highly experienced Life Science company located near Vienna which brings new innovative cancer tests for research and routine diagnostics onto the Life Science market. We are currently in the state of expanding our team and are looking for a dedicated and experienced team member .

Your Responsibilities

You are responsible for the overall PRODUCT QUALITY & Regulatory AFFAIRS of our invitro-diagnostic tests and devices in line with our QM system (ISO 9001 and ISO 13485).

This includes

- Lead CE-IVD marking of products according to In-Vitro Diagnostics Directive IVDD
- Lead implementation of In-Vitro Diagnostics Regulation IVDR and fulfilling regulatory requirements
- Accompany development projects, issuing development-accompanying and technical documentation for medical devices
- Support in the creation of technical documentation, revising already existing technical documentations
- Support in examination of the conformity and taking part in the conformity assessment
- Support in the certification process of our diagnostics tests and devices
- Communicate with responsible regulatory authorities (national/international) as well as with notified bodies
- Work in Post-Market Surveillance
- Support related departments, e.g. with internal trainings
- failure prevention, product safety and quality control testing (in process, finished goods);
- performance evaluation of our products;
- supervision of product manufacturing in compliance with regulatory requirements and our QM system;
- preparing of internal and external audits;

Your Qualifications

- Completed university studies in a relevant life science field, preferably in molecular biology, or a technical program;
- Experience with CE-IVD marking of diagnostic products
- Knowledge and implementation experience of ISO13485
- Relevant professional experience in the field of diagnostic test development;
- Experience in product quality management and regulatory affairs, product licensing and CE marking and good knowledge of the applicable regulations;
- You have general knowledge of diagnostic biomarker applications, and you are able to understand and articulate complex scientific literature and use extensive complex clinical data;
- You are a good team player, have excellent communication skills and are fluent in German and English.

Your Benefits

As our Manager Product Quality & Regulatory Affairs you will closely cooperate with the company management and have the great opportunity of actively participating in shaping our common venture. The minimum salary amounts to € 60 000.- gross per year for a full-time position. However, we offer a market-oriented excess payment in line with your qualifications, experience, and individual competencies.
Please send your cover letter and CV to m.rosenauer@oncolab.at.