ONCOLAB
Diagnostics GmbH solutions for personalized medicine

MANAGER PRODUCT QUALITY & REGULATORY AFFAIRS

We are a small but highly experienced Life Science company located near Vienna which is about to take off and bring 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 for our whole new laboratory.

Your Responsibilities

You are responsible for the overall **PRODUCT QUALITY (QA)** of our invitro-diagnostic devices in line with our QM system (ISO 9001 and ISO 13485). This includes

- preparing and updating the technical documentation files for our products (specifications, design plan, risk plan, safety reports, etc.);
- failure prevention, product safety and quality control testing (in process, finished goods);
- performance evaluation of our products;
- supervision of product manufacturing in compliance with GMP standards, regulatory requirements and our QM system;
- maintaining laboratory equipment accurately calibrated;
- supporting internal and external audits;

Furthermore, you are responsible for all **REGULATORY AFFAIRS** of the company in close cooperation with the management**.** This includes

- ensuring regulatory compliance and preparing submissions to authorities;
- medical device / vigilance reporting (incident reports and FSCA) to competent authorities and coordinating the necessary corrective actions;
- ensuring compliance with Post-Market Surveillance (PMS) obligations;

You will also support the management with respect to

- patent management, and
- soliciting research grants;

Your Qualifications

- Completed university studies in a relevant life science field, preferably in molecular biology, or a technical program;
- 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 € 51 800.- 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 info@oncolab.at.