**Reference number Aniling202206QM**

# Quality Assurance and Regulatory Affairs (QA/RA) Manager

## Job Description

**Aniling**, a biotech product company, is looking for a motivated **QA/RA Manager** to maintain and improve our company-wide quality management system that complies with the requirements of ISO 13485 and the regulation under which the products are certified. The successful candidate will support and interact closely with all departments in the company (design and development, project management, business development, etc.) providing expert regulatory and quality information to the whole team.

## Job duties

The job of the quality manager is to oversee the development, operation and certification of a company-wide quality management system (QMS) to ISO 13485 and beyond. Job duties include:

- Ensure that the Quality Management System requirements are effectively established and in accordance with the applicable in vitro medical device regulations
- Support product development life-cycle by providing expert input to the team of designers, and support the writing of the technical files and related documentation
- Coordinate internal and external audits from notified bodies and their follow up
- Manage CAPAs, non-conformities, root cause analysis, change control, and risk management, as well as control of documentation and records
- Support in management review, quality policy and objectives/KPIs
- Maintain expert current knowledge of European and foreign regulations, legislations, best practices and guidelines related to QA/RA
- Manage quality and regulatory affairs initiatives to drive best practices and continuous improvement in the company. Ensure that the personnel are well trained

## Required Skills and Experience

- Bachelor's degree in a life science, technical, or healthcare discipline or equivalent
- At least 2 years of work experience in a quality assurance and/or regulatory affairs role
- Familiar with applicable standards and regulations such as ISO 13485, 14971 & IEC62304
- Understanding of medical devices development and the clinical investigation process
- Excellent written and oral communication skills
- Strong project management skills and experience
- Ability to adapt to new challenges, learn quickly, and take action while engaging in a fast-moving, growing startup environment
- Comfortable working in a flat non-hierarchical environment
- Rigorous, organized, autonomous
- Strong MS Office skills

### Other desirable skills

- Experience with in-vitro diagnostic directive and/or regulation
- Knowledge of FDA and EU Regulations and Guidance, as well as global Regulatory Standards and associated ICH Guidelines
- Quality Assurance Audit certification
- Knowledge of agile methodologies (Agile, Lean, Kanban or Scrum)

## What we offer

- Immediate start
- Competitive salary according to qualifications and experience
- Flexible schedule in entrance and exit
- Internal trainings
- Collaborative network devoted to bring advances in genomics to medical applications
- Possibility for career advancement, specialized training courses and scientific meetings
- An excellent work environment with a young, dynamic collaborative team

## About our Company

Aniling S.L. is a biotechnological startup founded in 2014 in Badalona with the aim of improving genetic analysis to contribute to genomic medicine, mainly by accelerating the field of epigenomics. The company owns the GEUS technology, which unifies genetic and epigenetic sequencing and provides end-to-end solutions for the right treatment decisions in oncology.

## How to apply

Please send your application to **info@aniling.com.**

Applications should include:

- A CV including your contact details
- Names, email and telephone numbers of two referees
- A short statement of motivation

PLEASE QUOTE THE REFERENCE CODE **Aniling202206QM** ON ALL APPLICATIONS.

Position posted: June 23rd, 2022.

Applications will be reviewed on a rolling basis until the position is filled, and the pre-selected candidates will be contacted for interviews.