Ares Genetics (ARES) is a Vienna based digital health start-up that develops and commercializes next generation solutions for the diagnosis and therapy of infectious diseases and antimicrobial resistance (AMR). ARES builds on ARESdb, likely the world's most comprehensive proprietary databases on the genetics of AMR and its ARES Technology Platform, a unique artificial intelligence powered bioinformatics AMR platform. ARES recently initiated the development of in-vitro workflows and set-up of an R&D and service laboratory in Vienna for the development of ARES*upa*, a Universal Pathogenome Assay for rapid diagnosis of infectious diseases and antimicrobial resistances based on next generation sequencing.

For this R&D and service laboratory, we are currently searching for a

Laboratory Quality & Regulatory Manager (QA/RA) (m/f/d)
(Ref.-No.: 1201107)

for a staff function role in full-time employment at ARES in Vienna.

In your role as Laboratory QA/RA Manager you will lead quality operation for a NGS service laboratory in the field of infectious disease diagnostics.

Your responsibilities...

- Establishment and maintenance of the laboratory's quality management system in compliance with ISO 15189 and EU-IVD-R
- Partner with the Head of Laboratory in the development and implementation of departmental policies, SOPs and WIs
- Plan, coordinate, and direct the quality operations of the clinical laboratory to ensure accurate, quality-driven services are provided to assist clinicians in the diagnosis and treatment of patients with severe infections
- Develop and implement regulatory strategies for the laboratory's human diagnostic services
- Plan and implement regular quality trainings and competence evaluation of new and current laboratory personnel
- At a later stage, evolve the company's quality system to comply with EU-IVD-R, ISO 13485 and FDA 21 CFR part 820 for IVD development and develop and implement regulatory strategies for the company's IVD products for the EU and US market.

What you bring with you…

- Strong knowledge of clinical laboratory and IVD-related regulatory requirements (ISO 15189, ISO 13485, EU-IVD-R, FDA 21 CFR part 820).
- Demonstrated knowledge of current technical, quality control, and quality assurance procedures and laboratory information systems.
- Thorough knowledge of Quality Management and Performance Improvement principles and tools.
- Strong organizational and analytical skills.

- Thorough knowledge and use of appropriate computer applications to perform duties efficiently.
- Ability to meet changing conditions and utilize critical thinking skills to analyze and interpret data.
- Business-fluent knowledge of written and spoken English. Knowledge of German is an advantage, but not a requirement.

What you can expect…

- A varied and exciting challenge in one of the most innovative and rapidly growing segments of the healthcare industry.
- A young, dynamically growing start-up company with short decision pathways and a flat hierarchy.
- An inspirational environment at one of Europe's most prominent biotech clusters.
- An attractive and competitive salary package.

For legal reasons, we are obliged to inform you, that the salary package for this position starts at gross € 42,000 / year. Our salaries are nonetheless oriented towards market-based salaries depending on your relevant professional expertise and may be significantly higher.

We look forward to receiving your detailed application. Please include the reference number 1201107 and preferably submit it electronically to contact@ares-genetics.com.

Find further information on ARES here

- www.ares-genetics.com
- LinkedIn: https://www.linkedin.com/company/ares-genetics/
- Twitter: https://twitter.com/AresGenetics

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