



VACANCY

Quality Assurance Manager – Service lab

Cergentis is a genomics-focused biotechnology company and leading provider of genetic quality control solutions, based on its proprietary Targeted Locus Amplification (TLA) technology platform. With our widely published and recognized genetic analyses, we support all leading pharma companies and research institutes in the characterization and QC of their genetically engineered (animal) models, biopharmaceutical cell line development, and cell and gene therapy products. By helping our customers to de-risk R&D program decisions, minimizing time-to-clinic, providing objective genomic evidence to regulators, and supporting patient safety, we aim to support biopharmaceutical medicine programs worldwide.

To help further develop our Quality Management System (QMS) to the GMP level, we are currently looking for an energetic and talented **Quality Assurance Manager – Service lab**.

RESPONSIBILITIES

- Supporting in, and approval of investigation of out-of-specifications of Quality Controls
- Registration and approval of SOPs, Procedures and Work instructions of the Service lab
- Monitoring and registration of internal audit program
- Contribute to continuous improvement of the QMS of the Service lab
- Preparing Quality questionnaires for customers
- Provide Quality training to Cergentis personnel
- Apply and interpret compliance requirements
- Support and participation in customer audits and authority inspections
- Performing internal audits

REQUIREMENTS

- BSc or MSc degree in life sciences.
- Experience in an analytical pharmaceutical or biotech environment, preferably in Quality Control or Quality Assurance
- Knowledge of, and proven experience with working in the regulatory framework in the GMP environment (ICH, FDA, Ph. Eur)
- Pro-active attitude and good organizational and time management skills
- Fluent in English
- Team player
- EU citizen or work permit

OFFER

Working at Cergentis means working in an international and exciting environment. We are a young and dynamic team of talented people from all over the world. Our company culture is best described as informal - where hard work and team spirit are considered very important. You will be reporting to the Director of Quality Assurance and Regulatory Affairs.

You will be responsible for the quality assurance of high-end genetic products and services, primarily in the field of cell and gene therapy, to leaders in pharmaceutical industry and academia world-wide.

We offer an exciting and dynamic 0.8-1FTE job in a vibrant, fast-growing company with an excellent remuneration and opportunities for further personal development.

INTERESTED?

Please send your application letter and CV to vacancies@cergentis.com attn. Maaïke van der Weij, or contact us via the same email address for more information.

Acquisition in response to this advertisement is not appreciated.