

QA/RA manager

November 2018

1 Biogazelle

Biogazelle offers **genomic and transcriptomic services**, performed in an ISO accredited lab, to support **research, clinical trials and personalized medicine**. Our customers rely on our expertise in RNA biomarker discovery, development and validation; our pioneering role in **liquid biopsies** and **non-coding RNA**, and our experience with clinical trials to accelerate the development of their **diagnostics and therapeutics**. Our service portfolio is built on state-of-the-art technologies such as **RNA sequencing**, high-throughput **qPCR** and **digital PCR**, all combined with **advanced data analysis** methods.

Our quality system is fully compliant with the ISO17025 standard. In addition, the GCLP requirements are followed when conducting analysis in the context of clinical trials

Currently, we are looking for an **experienced QA/RA manager** to (1) operate the quality management system on a day to day basis and (2) to assure that our services are delivered in line with appropriate legislation and quality standards.

2 Function description

The QA/RA manager coordinates the maintenance of the quality management system and is responsible for implementing and operating the quality management system on a day to day basis. In addition, the QA/RA manager needs to assure that all services are delivered in line with appropriate legislation and quality standards. The QA/RA manager reports directly to the business unit manager.

Main responsibilities include:

- Ensure that all processes involved in the quality management system are defined and documented, and comply with the ISO/IEC 17025 international standard and GCLP guidelines
- Coordinating the company's document management system.
- Manage all employees and co-workers to ensure correct implementation (and follow up of all procedures) of the quality management system.
- Perform internal audits and prepare and host external audits.
- Identify relevant quality-related training needs and organize trainings
- follow up on complaints, nonconformities & deviations and monitor the effectiveness of the corrective and/or preventive action taken.
- Ensure the further maturation of the quality management system.
- Support in method, software and instrument validation

- Studying scientific and legal documents
- Keep track of ever-changing legislations (Belgium and abroad) that are relevant for the services delivered to our customers
- Formulate and implement regulatory affairs policies (including GDPR and biobank legislation) and procedures to ensure that regulatory compliance is maintained or enhanced.
- Provide regulatory guidance regarding design, development and implementation of biomarker assays in clinical trials

- Communicate regulatory information to multiple departments and ensure that information is interpreted correctly
- Monitor emerging trends regarding industry regulations to determine potential impacts on organizational processes

3 Competences and skills

- A master's degree in science
- Experience in ISO 17025 and/or ISO 13485 and/or ISO 15189 is required
- Working knowledge of ISO, EMA and US FDA quality system and regulatory requirements associated with the services provided by Biogazelle
- Must be able to understand, interpret and implement quality standards and regulatory guidelines
- Auditing experience, ability to lead internal audits
- Excellent organization and coordination skills.
- Ability to work independently as well as a member of a team
- Able to identify problematic situations, to communicate appropriately, to initiate problem solving processes and to propose remedial actions
- Excellent oral communication, reporting and presentation skills
- Must be able to interact in a professional manner with employees and all levels of management
- Fluent in English, written and spoken. Knowledge of Dutch is an advantage.

4 Our offer

- A financial package according to your experience, extended with legal benefits
- Professional development and training opportunities
- You will work in an innovative and stimulating environment

5 How to apply?

Please send your motivation letter and CV to hr@biogazelle.com

6 Contact

Biogazelle, Technologiepark 3, B-9052 Zwijnaarde