Vesale Bioscience, a Vesale Pharma spin-out, is dedicated to organizing the development, production and distribution of **bacteriophages**. Modern phage therapy is the most promising treatment against **antiobiotic multiresistant bacterial (AMR) infections, one of the biggest global health challenges, referred to as "the next pandemic" by the WHO. AMR is expected to become the single largest death cause within the next quarter century, surpassing cancer.**

Vesale Bioscience has developed "**Inteliphage**", a revolutionary automatic phagogram, IVD for a fast screening of phages. This equipment provides a diagnosis in three hours instead of the usual three days, allowing Vésale to recommend and deliver a personalized and highly effective treatment in record time, which is life-saving in many critical circumstances. In 2021, Vesale Bioscience received **the BioFIT award for the most innovative life sciences start-up in Europe**.

Vesale Bioscience has a close Research and Development collaboration in phage therapy with **The Belgian Defense (Queen Astrid Military Hospital)** and other major European Institutions. Find more information on https://phage.health

They are looking for that person who wants to be a valued contributor and member of a talented and dynamic team (M/F)

Quality Assurance Manager

As Quality Assurance Manager, you will be responsible for creating and supporting a quality culture across the company by driving compliance activities through product life cycle.
This includes driving the Quality and Compliance activities for the QMS implementation, audits, complaints, CAPA, continuous improvement, GMP/GCP/GDP compliance.
The QMS will cover not only the phagogram development which is a IVD device (outsourced production), but also the phage R&D, production (lab) and distribution.

Responsibilities:

- Support design, implementation, maintenance and continuous improvement of the QMS.
- Ensure the QMS is in place and is recognized, understood and maintained across the company.
- Define priorities, build processes and maintain applicable QMS sections to ensure consistency and compliance to IVDR, FDA and other regional legislation (China, Japan,…), as well as supervise GMP/GCP/GDP processes.
- Communicate internally on the QMS implementation and review progress
- Ensure compliance to Medical Devices and In-Vitro Diagnostics regulations, applicable ISO requirements from a quality, safety and efficacy point of view.
- Acts as Person Responsible for Regulatory Compliance (PRRC) as defined by IVDR requirements.
- Supervise the Person Responsible for GMP/GCP/GDP compliance from a quality, safety and efficacy point of view.
- Lead quality efforts in corporate development of analytical methods.
- Work closely with internal and external business partners in driving quality into the IVD pre- and post-market activities
- Ensure lab assets are maintained and inspected in line with standards and legal requirements
- Collect and analyze performance data against defined parameters and monthly reporting quality key performance indicators.
- Supervise the program of site internal auditing. Acting as primary contact for customer audits at site.

- Keep abreast of changes to quality regulations and guidelines, advising the management team of any business implication regarding these changes.
- Report to the COO.

Profile:

- You hold a master's degree in sciences, or equivalent through experience.
- Minimum of 7 years of experience in Quality in IVD/MD company(ies).
- Solid knowledge of regulatory requirements, standards and guidance associated to IVD products including but not limited to IVDR ((EU) 2017/746), ISO13485, ISO14971, ISO20916.
- Knowledge of GMP/GCP/GDP legislation is a plus.
- Qualification as lead auditor ISO 13485 / ISO 9001 is a plus.
- You recognized yourself as organized, analytical and autonomous.
- Demonstrated leadership and cross-functional team spirit. You work as an entrepreneur with a quality and result mind.
- You are familiar with IT tools (MS Office, SharePoint, Flowcharting software, Acrobat).
- Good written and oral communication skills in French and English.

Offer:

- A challenging position within a high-potential biotech company.
- The opportunity to take part in the development of robust modern solutions to fight antibiotic-resistant infections.
- An attractive compensation package in line with the position's responsibilities and your experience.

Interested?

Send your CV together with a short cover letter to recruitment@pahrtners.be.

Your application and related information will remain strictly confidential.