OPEN POSITION

QA / RA Engineer

Position type	☒ Permanent ☐ Fixed-term ☐ Internship ☐ Hourly
Percentage	☒ Full time 100% ☐ Part-time: %
Starting date	April 2020
Location	Lunaphore Technologies SA headquarters in Lausanne

Lunaphore Technologies is a life-sciences company delivering products based on a microfluidic technology to analyze tissue samples for cancer research and diagnostics. Lunaphore is seeking a highly motivated candidate to join our team and contribute directly to the development and growth of the company.

Summary

Lunaphore is seeking a highly motivated candidate to contribute to our company with his/her experience in quality assurance and regulatory affairs by managing and improving Lunaphore's Quality Management Systems and ensuring that the company's products meet all necessary regulatory requirements.

Role/Responsibilities

The Quality Assurance/Regulatory Affairs (QA/RA) Engineer is responsible for:

- Managing and improving the Quality Management System (QMS) of the company in compliance with ISO9001, ISO13485 and American 21 CFR Part 820.
- Ensuring compliance of the IVD and non-IVD products with regulatory and quality requirements.
- Performing technical quality inspections of Lunaphore's products.
- Frequently interacting with Lunaphore's critical suppliers.
- Meeting quality and regulatory-related deadlines as well as ensure up-to-date documentation.
- Participating to internal and external audits.
- Frequently interacting with the different departments to ensure compliance of the product development to regulatory and quality requirements.

- Supporting QA/RA department for RA activities.
- Reporting to the QA/RA Manager on a regular basis.
- Supporting the QA/RA Manager in contacting external parties such as notified body, competent authorities or consultants.

Skills

- You have an excellent understanding of quality and regulatory standards (experience with ISO13485, 21 CFR Part 820 and Directive 98/79/EC is a strong plus).
- You have experience with implementation or maintenance of a Quality Management Systems.
- You have the ability to adapt in a constantly changing environment.
- You like to interact with people in a multi-disciplinary environment.
- Excellent organizational skills, attention to detail, ability to manage deadlines, multiple priorities, and deliver results with limited supervision.
- An excellent command of written and oral English. French is a strong plus.
- You have excellent knowledge of Microsoft Office software programs (Word, Excel, PowerPoint).

Preferred qualifications

- A degree in a Life sciences/Engineering related field and/or a certificate in Quality Assurance and Regulatory Affairs.
- 2-3 years of experience in Quality Assurance and/or Regulatory Affairs for Medical Devices / In Vitro Diagnostics Medical Devices.
- Internal Auditor certificate.

We offer

- A young and strongly growing high-tech scale-up company.
- An international working environment with a high level of diversity and a strong network.
- A highly interactive team with strong personal and technical qualities.

Contact information

If you are interested, send your application to: human.resources@lunaphore.com