



Quality and Regulatory Affairs Manager

 Lunaphore Technologies SA

 Tolochenaz (Vaud), Switzerland

Job title: Quality and Regulatory Affairs Manager

Reports to the: VP Operations

Activity rate: 100%

Type of contract: Permanent

Start date: 01.01.2022

Duration: N/A

About our company

Lunaphore Technologies is a young scale-up active in the Life Sciences field developing products based on a microfluidic technology to analyze tissue samples in immuno-oncology research. Lunaphore is seeking a highly motivated candidate to join our team and contribute directly to the development and growth of the company.

Job overview

We are looking for a QA/RA manager to lead the quality and regulatory affair activities in Lunaphore. The QA/RA manager will be responsible for the QMS of the company and will also ensure that Lunaphore products meet all necessary regulatory requirements. The QA/RA manager will coordinate the QA/RA team, working in closed collaboration with the Supply Chain, the Manufacturing, and the R&D departments.

Responsibilities and duties

- Maintain the Quality Management System (QMS) of the company in compliance with ISO9001
- Ensure compliance of Lunaphore products with the applicable regulatory requirements.
- Be responsible for the final product releases for customers
- Be responsible of customer complaints
- Coordinate and manage external audits, internal audits and supplier audits.
- Interact with the R&D Team to ensure compliance of the product development to regulatory and quality requirements
- Manage contacts with external parties such as notified bodies, competent authorities or consultants
- Be responsible for the Quality agreements with distributors and suppliers
- Leads QA/RA team and influences other cross-functional teams
- Recruitment, training, evaluations and professional development of the team members.

- Responsible for Quality KPIs
- Report the progress of the team's work to the VP Operations
- Support the VP Operations to plan, administrate and monitor the QA/RA department annual budget

Required qualifications

- A degree in a Life sciences/Engineering related field and/or a certificate in Quality Assurance and Regulatory Affairs.
- 5+ years of experience in QA/RA activities.
- Experience with mechanical/electronic devices and/or microfluidic chips and/or chemicals.
- Experience with Medical Devices and/or IVD.
- Experience in ISO 9001
- Experience in people and project management
- Experience in financial aspects of production is a plus
- Fluency in English (at least C1), French / German / Italian is a plus.

Required soft skills

- Demonstrated ability to run a high-quality organization, strong organizational skills and experience in root cause analysis
- You like interacting with people, bring advice and solutions to them, and demonstrate excellent communication skills.
- You have excellent leadership and interpersonal skills to lead a team
- You have excellent project management skills
- You can manage multiple tasks in an autonomous and efficient way
- You can collaborate with others by working in a team, share information with peers and superiors.
- You demonstrate excellent organizational skills and attention to details.

We offer

- A young and strong-growing high-tech company.
- A diverse and international working environment with a strong network.
- A highly interactive team with strong personal and technical qualities.


How to apply

Send your complete application through human.resources@lunaphore.com

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