



Job Description: **Quality Manager - CDI**

At Abbelight we are driven to advance biological and biomedical research by making powerful super-resolution microscopy easy and accessible for all users. Together with researchers, biotech labs and medical facilities, we aim to unlock the next generation of imaging tools to understand biology and help improve human health.

We are looking for a quality manager to spearhead our quality assurance and regulatory affairs. You will be the "owner" of all matters quality-related, working closely with senior regulatory consultants to design and implement a quality program at abbelight,

THE ROLE

You will be responsible for ensuring that our products are **reliable, standardized, and respect the appropriate regulatory norms**. You will work with all the various divisions of the company, from software and hardware R&D to production and customer service, to improve our existing products and provide guidance on the product roadmap.

Some of your missions will be to:

- Assist management in the **definition of the quality policy** and the deployment of continuous improvement.
- Set up the **quality assurance system** for design & manufacturing of instrumentation and reagents (ISO13485)
- Ensure **compliance & certification readiness**, handle internal **audits**.
- Conduct the **management review**.
- Develop, implement, and maintain **training programs** for staff.
- Support the Data Protection Officer in the implementation and maintenance of **GDPR** compliant processes.

REQUIRED PROFILE / SKILLS

- **Master's (BAC+5)** acquired in the biomedical domain
- **Minimum 2-3 years of relevant experience** in the biomedical domain.
- Good understanding of relevant **regulatory norms**, ie. ISO13485, ISO9001, ISO62304, CE Label
- Knowledge of European RIVD/RDM.
- (Desired) Familiarity with **design processes** and techniques (5 Why's or other six-sigma tools)
- Strong oral and written communication in English and French.

WHY ABBELIGHT / WHAT WE OFFER

TEAM A passionate, multidisciplinary, multicultural and quickly growing team, based just outside of Paris.

STABILITY Permanent position (CDI) with health benefits, and the French work-life balance.

EVOLUTION Your role is flexible and can evolve in multiple directions as the company grows. Early on you may assume managerial responsibilities to train and integrate more junior team members.

FLEXIBILITY Work primarily **on site** in our office just outside of Paris, with flexibility for **remote** work as necessary.

HOW TO APPLY

Send your CV and a brief explanation of *why this job is a good fit for you* to cbutler@abelight.com.

WHO WE ARE / ABOUT ABBELIGHT

Founded in 2016, abbelight is a fast-growing start-up specialized in super-resolution fluorescence microscopy, specifically Single Molecule Localization Microscopy (SMLM). The technology developed by abbelight is based on three areas of expertise: chemistry, optics and computer science. The products developed integrate a constantly evolving know-how and allow abbelight to offer a complete solution, from sample preparation to data analysis, including modular instrumentation that can be adapted to customers' needs. See also: www.abelight.com