



# Quality Assurance Specialist

**Paris, France**

**monia@elemed.eu**

## The company

Are you passionate about innovative products? Would you like to be part of something that will save lives?

This company is for you! They are the pioneer in the development of a cutting-edge pacemaker solution. This French startup is developing a pacemaker that incorporates a revolutionary energy harvesting module capable of powering the device with no energy life limitation! This is a wonderful chance to be part of this journey and have a huge part in this revolution. They are located in the wonderful capital Paris!





## The opportunity

This is your chance to work with implantable devices Class III in the cardiovascular industry and be part of something that will have a real impact on the Medical Devices industry.

You will be working closely with the engineers to develop these products. That will also be an opportunity to follow the all process from A to Z and have your word!

## The responsibilities

As a Quality Assurance Specialist you will:

- Continue the implementation, maintenance, and improvement of the QMS
- Support the development of the Regulatory Dossier for our pacemaker system
- Potential overlap with validation activities such as IQ, OQ, PQ
- Management of the Risk Management File including Usability and application of the applicable technical standards for risk reduction
- Assist in the safety testing of the product for risk reduction to the state of the art
- Work cross-functionally in identifying and resolving miscellaneous quality issues, participate in CAPA management
- Quality /Regulatory review of technical reports
- Conduct internal and supplier audits
- Assist in audits and follow-up of results



## Your qualifications

- Minimum of 3 years experience in Quality Assurance within Medical Devices
- Extensive knowledge of QMS
- Fluent in English and French

## Interested?

Please send your CV to [monia@elemed.eu](mailto:monia@elemed.eu) to arrange a confidential career discussion.

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<https://www.elemed.eu/vacancies/>