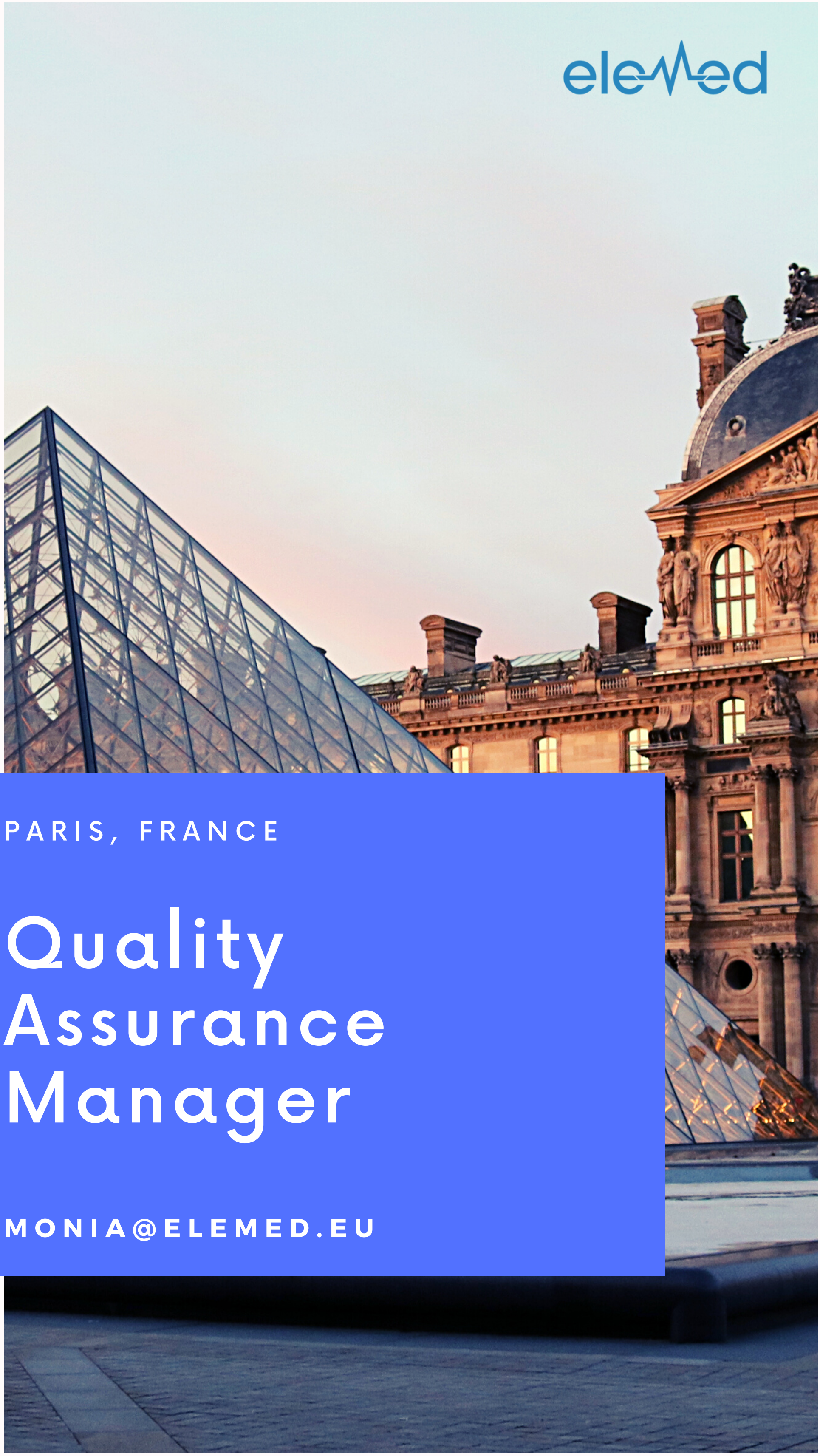


PARIS, FRANCE

Quality Assurance Manager

MONIA@ELEMED.EU

The company

Are you passionate about innovative products? Would you like to be part of something that will save lives? Then this is the company for you!

They are the pioneers in the development of cutting-edge pacemaker solutions. This French startup is developing a pacemaker that incorporates a revolutionary energy harvesting module capable of powering the device with no energy life limitation!

It’s a wonderful chance to be part of the journey and have a huge part in the revolution this company is creating. What more? They are located in cosmopolitan Paris!

The opportunity

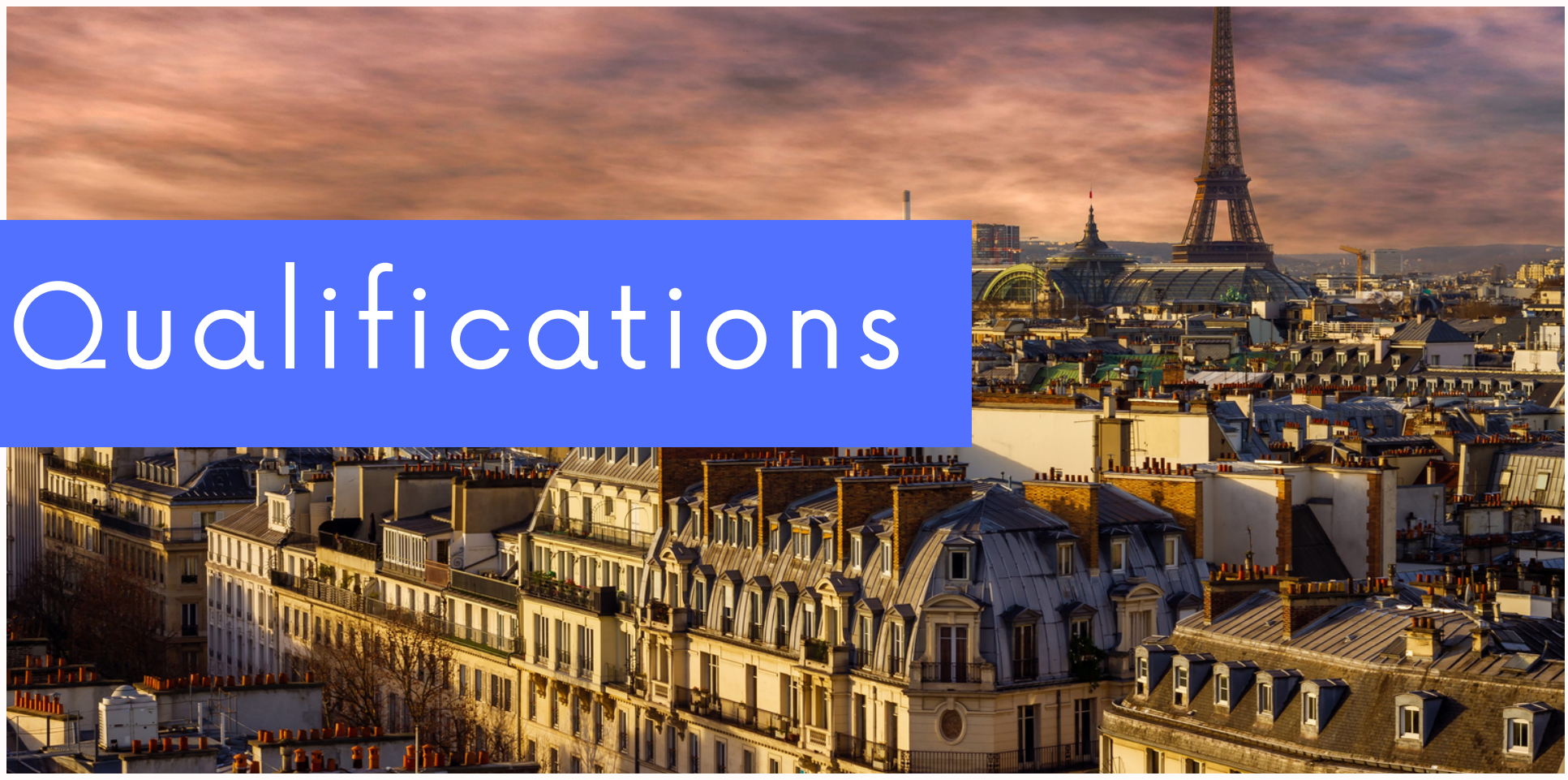
This is your chance to work with implantable devices Class III in the cardiovascular industry and be part of something that will have a real impact on the Medical Devices industry.

You will be working closely with the engineers to develop these products. This will also allow you the opportunity to follow all the processes from A to Z and have your word.

Responsibilities

As a Quality Assurance Manager you will:

- Establish a new quality management system QMS
- Work with regulatory affairs to prepare MDR certification
- Realization and successful certification of a full ISO 13485 QMS when all chapters become applicable
- Develop and maintain the necessary procedures
- 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
- Promote a quality culture across the company
- Quality/Regulatory review of technical reports
- Conduct internal and supplier audits
- Define criteria for a potential external eQMS version
- Assist to audits and follow up of results



Qualifications

- Technical or engineer or scientific background
- Minimum of 5 years experience in Quality Assurance within Medical Devices
- Experience in a QMS leading function or in multiple areas of QMS
- Fluent in English and French

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

MONIA@ELEMED.EU

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