VICE PRESIDENT REGULATORY AND QUALITY ASSURANCE

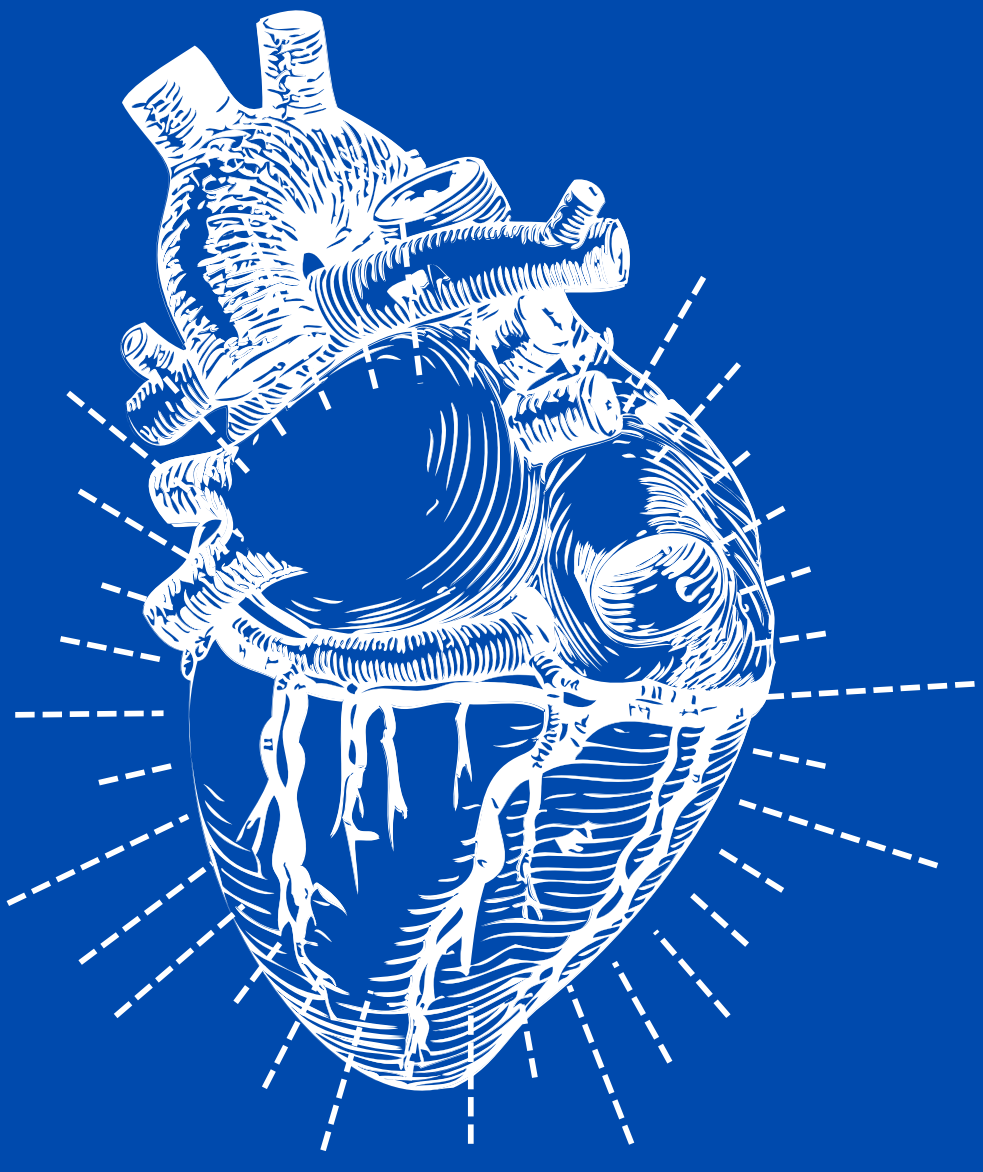
PARIS, FRANCE

eleMed

THE COMPANY

Join a well established, start-up company designing, developing and producing a Class III active implantable medical device that changes the lives of patients. If you are looking for a role with a large team to manage, this position is not for you. But if you want to develop your own team this role will be perfect! This role is all about being hands on with the product and working in a tight knit team with one vision, surrounded by other senior experts in their field.

You can be sure that no two days will be the same! You'll enjoy a wide variety of responsibilities covering various elements of Regulatory and Quality management, fast moving decisions and the chance to be the main point of contact for FDA and Notified Body communications.



ACTIVITIES

Reporting directly to the CEO, you have the responsibility to develop and implement quality plan and regulatory strategies aligned with business strategy. You are instrumental in turning a technological marvel into a medical revolution in treatment of heart failure and one of the greatest success stories and of the medical device industry of the 21st century.

In particular, your responsibilities cover:

- Manage regulatory submissions and interactions:
  - as part of upcoming clinical trials in the US (FDA submissions, Q-Sub, Breakthrough Designation, EFS/IDE) and Europe (national competent authorities, notified body, European Commission expert panel)
  - ultimately as part of market approval, with the goal to secure FDA market approval (PMA) and CE Mark (under MDR)

- Develop an agile, efficient, robust, and process-driven quality system that covers company's activities (design, manufacturing, clinical) and comply with US/European regulatory requirements and applicable standards
  - Drive the development, implementation and monitoring of quality system policies, processes, procedures across the company
  - Implement the proper the quality management system software suite
  - Create, implement and manage a quality / regulatory training program for employees
  - Secure and maintain ISO 13485 certification

- Partner with other departments (R&D, Manufacturing, Clinical Affairs, Marketing) to meet efficiently user and regulatory requirements, in particular:
  - Develop and maintain a robust risk management system, throughout the product life cycle
  - Work closely with R&D as part of the design control system, to prepare the preclinical validation plan, risk management and regulatory standards compliance leading to compilation of technical dossiers to support regulatory submissions.
  - Review and provide inputs to clinical studies, ensure ethical compliance and manage transparency reporting (e.g. Sunshine act)
  - Ensure that training, technical (labeling, IFU, etc.), and marketing materials communicated externally are compliant with regulations

- Expand and manage the quality and regulatory internal team and external consultants

These responsibilities could be extended to clinical affairs/operations depending on the candidate's profile.

WHY THIS COMPANY?

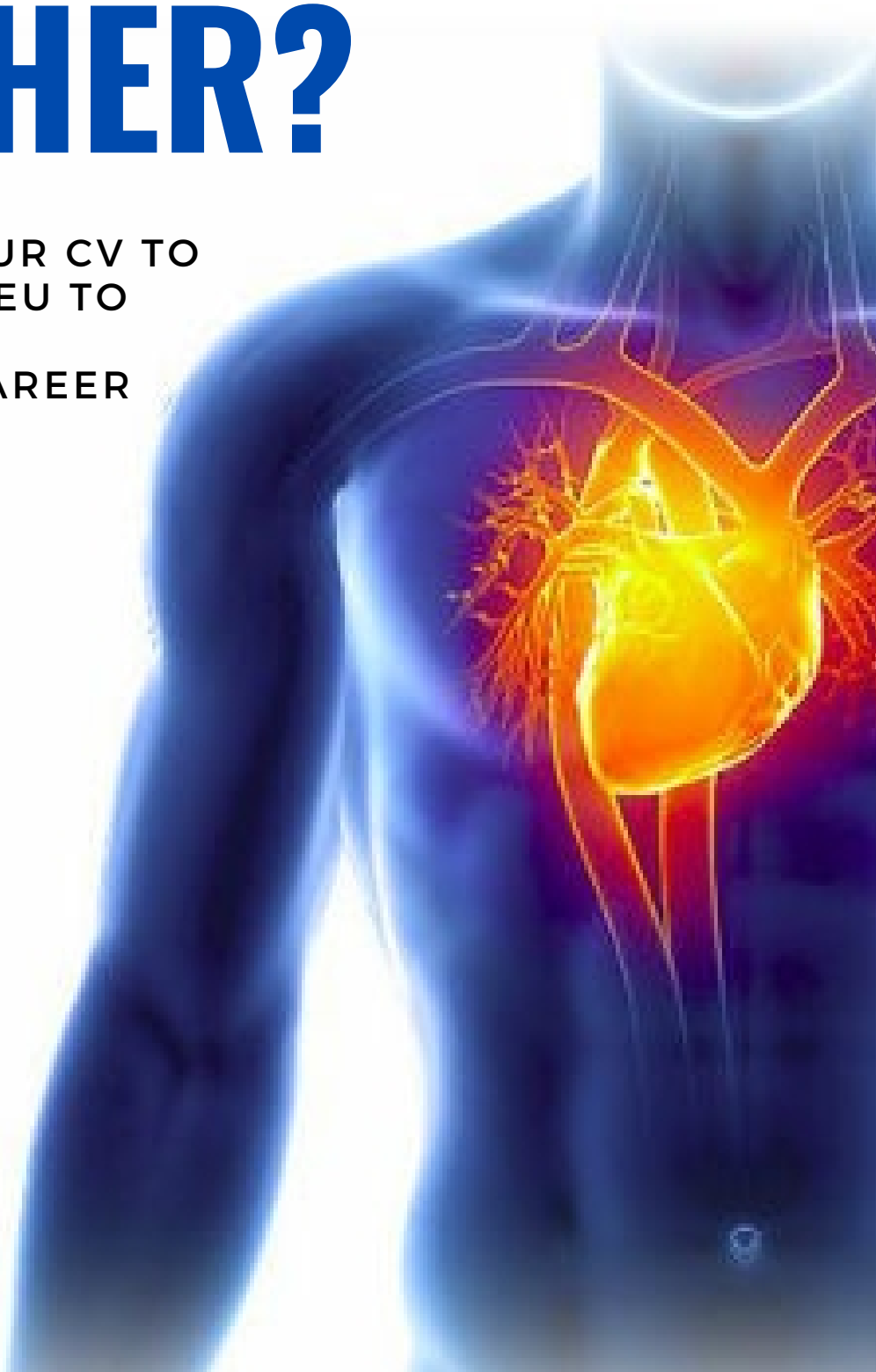
You will work with products resulting from over 10 years of R&D led by world-class scientists and engineers and about 50 employees of about 10 different nationalities.
The company is funded by leading international investors and has received the first direct equity investment of the European commission.

REQUIREMENTS FOR THIS ROLE:

- Minimum 15 years of experience in European / international regulatory and quality functions related to Class III medical devices, (preferably active implantable devices) and including supervisory or management experience overseeing highly skilled personnel.
- Experience of interacting with notified bodies, European competent authorities (BfArm, ANSM in particular), and FDA. Hands-on experience with EFS and breakthrough designation process would be a strong asset.
- Proficiency in interpreting European, FDA (and other major international regulatory bodies) regulations as they apply to the company.
- Experience acquired ideally in both large multinational medical device companies and in small organizations or start-up firms; good overall vision of how to develop QMS and regulatory strategy and bringing a company through pre-clinical, clinical and commercial stage.
- Working knowledge and operational experience with applicable standards, including ISO 13485, ISO 14971, ISO 14708, ISO 14155, ISO 10993, EN 45502 and MDD / AIMDD as well as 21 CFR part 820.
- Previous experience in commercial stage (market surveillance); QA management at a production site would be a plus.
- Strong written and verbal communication and interpersonal skills in English and preferably one other language.
- Flexibility to work in a start-up fast-paced environment, requiring efficient use of resources are required for success in this position. Hands-on approach while being capable of strategic planning and organisation.
- The successful candidate will be highly motivated, hard-working, autonomous, team oriented, and driven by a positive and entrepreneurial attitude. They will demonstrate strong leadership capabilities.

INTERESTED TO EXPLORE THIS FURTHER?

PLEASE SEND YOUR CV TO MONIA@ELEMED.EU TO ARRANGE A CONFIDENTIAL CAREER DISCUSSION.



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