HEAD OF QA/RA

BARCELONA, SPAIN

THE COMPANY:

This start-up is breaking barriers and revolutionising the therapy available for neuromodulation and brain restoration with their unique bioelectrical implant. With their flagship company recently securing €1 billion to bring the product to market, they are looking towards the future and leading the way in neurotechnology.

Led by some of the finest scientific and technical experts in the neurological space, this is a fantastic opportunity to learn from the best whilst directly impacting the future and direction of the organisation from a Quality and Regulatory perspective. Their team is very diverse coming from all over the world and even though they have high ambitions, they understand the importance of a fun working environment so installed an Italian coffee machine and pool table!

THE ROLE:

As the company is now doing their first in-human trials, they are looking for a Head of QA/RA to join them in a brand new role. It's a fantastic opportunity to really build something from the ground up and shape the role to leave your mark on the business. You will build a QMS from scratch and drive the regulatory strategy navigating the MDR and US regulatory landscape. As the medical device is a highly innovative Class III active device, you can guarantee that you will be presented with challenges and hugely develop yourself professionally.

ACTIVITIES ASSOCIATED WITH THIS ROLE:

- Build, implement and maintain the Quality Management System for development and manufacturing of Class III medical devices from scratch
- Outline the strategy to get certified according to ISO 13485
- Write and have responsibility for SOPs and processes such as CAPA management, document control, change control etc
- Define the regulatory strategy to obtain product approval in the European and US markets
- Liaise with competent authorities and notified bodies to drive the global regulatory strategy and obtain regulatory approvals
- Plan and execute internal and external audits and quality training
- Support the clinical team with clinical trial submissions

elemed

WHY THIS COMPANY?

- Work alongside a high-quality leadership team who come from scientific and technical backgrounds and have experience from some of the top MedTech giants
- Diverse company with team members from around the world
- Leading a new revolution in neuro-electronic systems with their Class III, highly innovative medical device
- Have a direct strategic impact on the business and direction of the company with regards to regulatory and quality
- Fun office environment with Italian coffee and pool table!

THE IDEAL CANDIDATE FOR THIS ROLE WILL HAVE:

- 5+ years of experience in the medical device industry in Quality or Regulatory function
- Experience building a Quality Management System from scratch in the medical device industry
- Minimum Class IIb medical device experience
- Extensive experience working in a start-up environment
- Working knowledge and awareness of the regulatory landscape and requirements

If you think you can bring any of the above to Elemed we would LOVE to hear from you!

Send your CV to kristina@elemed.eu for a confidential career discussion.
Good Luck!