BIOINDUCTION

JOB DESCRIPTION – QUALITY ASSURANCE AND REGULATORY AFFAIRS MANAGER

We are looking for a person from a technical background - electronics, biomedical physics or a similar engineering discipline, to be the internal lead and manage the team dealing with all quality assurance, and issues relating to achieving regulatory compliance.

Responsibilities

- Manage the QARA team
- Author and refine procedures, instructions, templates, and our quality manual to maintain our ISO 13485:2016 certificate.
- Author and refine technical documentation necessary to maintain our current CE Markings and to complete a design dossier suitable for submission for new products.
- Maintain and monitor our quality system within the company: changes, CAPA, Non-conformities, Complaints, PMS, continuous improvement, trend analysis, etc.
- Train all employees to the QMS, and assess skills, knowledge and QMS application.
- Perform internal audits to assess the company compliance with our QMS.
- Contribute to maintaining quality system related documentation including supplier records, audits, purchase and manufacturing batch information.
- Work with our Notified Body to maintain current certifications and achieve award of a CE mark and FDA approval on new products.
- Work with external consultants whenever necessary.
- Build knowledge and maintain surveillance of the many relevant quality standards.
- Provide technical support and resolve quality issues with suppliers, customers or auditors including introduction of new or re-designed components and processes.
- Present technical data to internal / external audit and inspection groups as required.

Personal qualities

- Ability to prioritise and make decisions.
- Good problem-solving abilities – able to identify salient issues, consider alternative solutions and evaluate the most appropriate course of action.
- Positive attitude toward change, and contribution to new ideas and improved ways of working.
- Excellent oral, written, cross functional and interpersonal communication skills that are appropriate for various levels, including management, staff, contractors and clients.
- Strong organisational and team-working skills including commitment and flexibility.
- Sound work ethics.
- Looks beyond boundaries of own job to support others.
- Excellent attention to detail and working knowledge of appropriate regulation and good manufacturing practices.

Experience/qualifications

- Master's level (ideally in engineering).
- Experience in Quality Management System (ideally 5 years, 3-5 may be considered).
- Experience in highly regulated environment (healthcare, aerospace, defence).

Details

- Location: Bristol.
- Full time.
- Reporting to Bioinduction Ltd CEO.
- Salary: depending on experience.

About Us

Our company mission is to **widen adoption of neuromodulation therapies** by:

- Enabling simpler, safer and shorter Deep Brain Stimulation (DBS) procedures.
- Developing new indication for DBS in treatment of dementia, hypertension and stroke in markets that have a substantial unmet need.
- Development of additional neuromodulation devices based around proven technology.

Bioinduction Ltd is developing a deep brain stimulator to treat Parkinson's disease and is investigating new DBS indications. We have designed and developed the only general-purpose deep brain stimulator (DBS) small enough to be implanted in the skull. We presently involved in two in-human clinical trials and are focusing our efforts on achieving European regulatory approval.

Finetech Medical Ltd is Bioinduction's sister company and has a 25-year history manufacturing the SARS implantable device for restoration of bladder and bowel function after severe spinal cord injury. It is the only company in the UK with clean room manufacturing facilities approved under the Active Implantable Medical Devices Directive (AIMDD).

With a management team of successful entrepreneurs, we are funded by UK government grants and private investors from the medical industry. This is an opportunity to be involved in exciting and rewarding work with leading-edge technology, while also making a genuine contribution to transforming the life of many people, and to join a fast-growing company at an inflection point.

How to Apply

If you have the skills and experience required and are interested in applying for this position, please attach an up to date copy of your CV and email maria@bioinduction.com