

## **JOB DESCRIPTION – SENIOR BIOMEDICAL ENGINEER**

### ***6 MONTHS MATERNITY LEAVE COVER – POSSIBILITY TO CONSIDER FULL TIME CONTRACT***

We are looking for a biomedical R&D engineer to support design/development of products and support manufacturing under a quality assurance system ISO 13485 certified. You will be responsible for mechanical design, V&V testing and technical documentation of active implantable devices for both current and new products.

### **Responsibilities**

You will be part of a small multidisciplinary team aiming at bringing DBS devices to the market.

- Apply your problem-solving skills to mechanical testing, test development and product improvement
- Carry out and document design development activities in accordance with ISO13485 and ISO14971 Risk Management
- Develop test methods, prepare V&V test plans and get involved in testing
- Assist the manufacturing team with process validation (including IQ, OQ, PQ protocol and report writing, sample size assessment, ...) and troubleshooting (tooling improvement, change of suppliers, ...)
- Liaise with suppliers for prototype purchases, delivery, non-conforming product reports, corrective actions, ...
- Compile technical submission documents necessary to maintain our current CE Markings and to complete a design dossier suitable for submission for new products (for CE-marking and FDA application)
- When necessary, assist with the training on updated build instructions, goods-in inspection instructions or production test instructions
- Manage interns
- Contribute to maintaining quality system related documentation
- Work with external consultants whenever necessary
- 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 facts, consider a number of alternative approaches and evaluate the most appropriate course of action
- Positive attitude toward change, and contribution to new ideas and improved ways of working
- Strong organisational and team-working skills including commitment and flexibility
- Demonstrate 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

- Bachelor's or Master's degree or equivalent
- Background in mechanical, biomedical engineering or related
- 3-5 years' engineering experience working in highly regulated environment (healthcare, aerospace, defence), ideally medical engineering
- Experience with the design development process to ISO13485
- Experience with risk management process to ISO14971
- 3D CAD software
- Understanding of process validation
- Good writing and communication skills

## Details

- Location: Bristol
- Full time, starting in May/June 2019
- Reporting to Bioinduction Ltd CEO
- Salary: depending on experience
- Possibility to transform into a full-time contract at the end of the maternity cover

## 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

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 are now positioned to start our first in-man clinical trial 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 a tipping 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 [helene@bioinduction.com](mailto:helene@bioinduction.com)