Neuronostics

Applicant Pack

HEAD OF REGULATORY AFFAIRS

UP TO £60K DEPENDING ON EXPERIENCE

November 2022

Neuronostics

Introduction and welcome from our Managing Director

Thank you for your interest in Neuronostics and our Head of Regulatory Affairs (HRA) role. This exciting role within our senior team is a new position that will be central to delivering our mission to revolutionise diagnosis and prognosis of neurological conditions.

The NHS is facing significant challenges in capacity and care. The COVID-19 pandemic has accelerated rising waiting times for neurology services: a 5,000% increase in people waiting over a year since the pandemic started. Against this backdrop, we believe Neuronostics can help healthcare practitioners and people with suspected neurological conditions alike. We are developing an exciting platform solution that will have a significant impact on quality of life: accelerating time to diagnosis, reducing uncertainty and increasing clinical objectivity.

Our primary focus is on epilepsy: a serious brain disorder that affects over 600,000 people in the UK alone. Here we have developed the first digital biomarker of epilepsy (BioEP) that can reveal the risk of future seizures from short segments of routinely acquired brain data. To support home management, we are developing a smartphone app that integrates information from wearables (such as smartwatches and wireless EEG headsets).

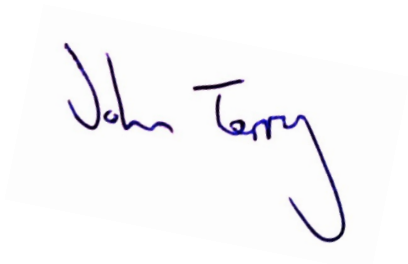
The major goals you will focus on in the next 2 years as our HRC include:

- Achieving CE Mark for Neuronostics Platform (including a successful external audit)
- FDA approval for NN Platform (following a well-orchestrated pre-submission process)
- Leading new device certification for new components of the platform (including a smartphone app and a wireless EEG headset)

Founded in 2018 by Dr Wessel Woldman and myself, Neuronostics has grown rapidly in the years since, supported by over £2M in research funding, as well as an over-subscribed pre-seed round of £300K in April 2021. We now employ 12 people and we will double in size in the next 12 months as we accelerate our market expansion activities.

Best,

Professor John Terry,
Neuronostics Managing Director



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+44 (0)117 457 2292 / info@neuronostics.com
Engine Shed, Station Approach, Temple Meads, Bristol BS1 6QH

Our mission, vision and values

At Neuronostics, our mission is to revolutionise the way neurological conditions are diagnosed, treated, and monitored. We use the power of mathematical modelling to develop novel digital biomarkers that create faster paths to diagnosis and effective treatment response.

Our vision that digital biomarkers are used routinely in neurology centres around the world to create a more proactive and anticipatory model of care radically improving the lives of people at risk of, suspected of, or living with neurological conditions.

To achieve our vision Neuronostics is grounded in the following values:

Partnership: We work with specialist healthcare professionals, researchers and, most importantly, those with direct lived experience of neurological conditions. Engagement with stakeholders drives us and must drive you.

Innovation: Our innovative solutions require new ideas and imaginative thinking. We actively encourage all members of staff to contribute to ideas generation and translation into new solutions.

Rigour: Our technologies are built upon high standards of scientific rigour and academic peer review. Having each other, as well as external experts, critique our work is essential in driving the breakthroughs needed.

Respect: Neuronostics staff have diverse expertise and backgrounds. Respect for each other, and for those we work closely with, is key to ensuring that everyone is listened to and can contribute to make our technologies the best they can be.

Accountability: We passionately believe that Neuronostics should be accountable to all our stakeholders and that our employees should be accountable to each other. Owning our failures, as well as our successes, is essential for our company to grow sustainably.

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The role of Head of Regulatory Affairs

This is an exciting opportunity to provide regulatory leadership to Neuronostics at a time of significant growth and international expansion.

We are looking for a dynamic and proactive individual to lead all of our regulatory activities. Reporting to the Managing Director, you will lead and be accountable for the regulatory and compliance activity of the company. You will ensure the identification and satisfaction of relevant standards required for enabling market access for company products across its major market territories.

As the Head of Regulatory Affairs, you will have a deep understanding of the quality standards which must be met for our key market access (UK/EU/US) to be achieved and maintained. As we are developing Software as a Medical Device (SaMD) healthcare products, you will need to be aware of the working practices/tools used when developing software and be comfortable working closely with technical staff. You will also thrive working in a start-up environment, happy to learn on the job, adapt your approach as new opportunities emerge and lead from the front as required in a small, but rapidly growing team.

In this role you will:

- Play a key role in developing company strategy as a member of the Neuronostics leadership team
- Act as an ambassador for Neuronostics, ensuring Neuronostics is part of the conversation both regionally and nationally on topics of regulation and compliance
- Lead company relationships with regulatory consultants and other 3rd party suppliers as appropriate
- Seek opportunities to grow our regulatory and compliance team through applications for grant funding
- Be responsible for all company regulatory requirements
- Lead the company regulatory strategy ensuring its alignment to the product roadmap

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In this role you will (continued):

- Maintain our QMS processes, report on QMS performance, promote regulatory requirements and support top management.
- Liaise with external bodies such as EU Notified Bodies (NB) or UK Approved Bodies (UKAB) as the named individual.
- Develop and manage policies and procedures which are a requirement for regulatory compliance
- Conduct research and analysis of regulatory requirements and policies for markets (usually the US, the UK, Canada and Germany) that the company is looking to enter with existing and future products
- Ensure the company systems and products meet the relevant quality and regulatory standards, monitoring regulatory developments and changes to ensure continued conformity with evolving requirements
- Working with the Chief Technology Officer, ensure the accurate and timely creation of technical and information governance documentation required to maintain product market access
- Working with the Clinical Safety Officer, ensure risk assessments are performed to required standards
- Working with the Product Team, ensure that Neuronostics' products are developed with a complete understanding of the regulatory landscape in which they will ultimately be deployed
- Working with the Head of Clinical Operations to take the lead on data management for the clinical studies, specifically EDC setup and management to be compliant with EU Clinical Trials, FDA and GCP regulations
- Lead ISO certificate audits especially ISO 13485 Audits
- Identify and report on quality KPIs to the board

This list of duties is indicative, and the final set will be agreed upon with the preferred candidate.

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Essential experiences:

- First degree in a relevant field
- Experience regulating MedTech products, ideally Software As a Medical Device and/or AI powered solutions
- Experience with securing approvals and successful external audits from bodies including FDA / EU MDR / UK MHRA / CE Mark / UK CA / CDMR / ISO 13485 / ISO10993
- Developing and maintaining our Quality Management System (QMS)
- Meeting NHS standards in clinical risk management - DCB0129/0160
- Keen eye for detail and exceptional presentation skills
- Trained to ISO 13485 internal auditor standard

Desirable experiences:

- Defining regulatory strategy for company products and conducting research to understand the regulatory landscape in target markets
- Patient focused products and end user medical devices
- Qualified to act as Person Responsible for Regulatory Compliance (PRRC) per Article 15 of the EU Medical Device Regulation (MDR)
- Certified ISO 13485 Lead Auditor

We recognise that most candidates will meet only a subset of these criteria and we value an open conversation about strengths, experience and areas for future development.

What we can offer you:

- A key leadership role with the opportunity to actively shape the development of a rapidly growing digital MedTech company looking to make a huge positive impact on the world;
- A flexible working model that enables you to work when you are most productive;

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- A competitive salary of up to £60K reflecting your level of experience and success;
- Company Pension Scheme (you contribute 2% and the company 7% on qualifying earnings);
- A dynamic and collaborative environment, where curiosity and innovation are encouraged and rewarded;
- A diverse and highly experienced team combining scientific, technical and commercial expertise;
- Key leadership role with the opportunity to actively shape the development of Neuronostics;
- 25 days annual leave, plus public/bank holidays. Staff members also receive an additional day off to celebrate their birthday;
- Access to ongoing professional development;
- Regular staff events and company away days.

We operate a hybrid working model, blending time in the office with working from home. Please note that as a key leadership role in our rapidly growing company, regular time in our Bristol offices will be expected. The Engine Shed is located right outside Bristol Temple Meads.

How to apply:

Applicants are encouraged to get in touch early for an informal chat about the role. Contact recruitment@neuronostics.com to arrange this!

An application consisting of a CV and accompanying cover letter outlining how your skills, experience and future career plans align with what we are looking for should be sent to recruitment@neuronostics.com.

Applicants will be considered on a rolling basis until the position is filled.

We look forward to hearing from you.