Quality Assurance and Regulatory Affairs Manager

*Your mission is to help us build a [**compliant**] human digital twin*

Healthcare systems face growing pressure to do more with limited resources. To address this, we must shift towards proactive healthcare—prioritising early detection and prevention.

To meet this challenge, we must use the massively growing amount of healthcare data to support clinical decision-making. We are solving this by translating various data streams into clinically-actionable insights that support overstretched clinicians identify patient health changes earlier. Over time, we are personalising this to ultimately build *your human digital twin.*

This is a "right time, right place" kind of moment, with increasing momentum, multiple hospital partnerships, vast data access, a first product in clinic with early positive results, and imminent regulatory approval (Class 2 EU:MDR). Now, we are looking for you to take us to the next level.

We are building a company that wants to change the way healthcare innovation is brought to market and are looking for people to help us do just that.

Are you up for the challenge?

About the role

You will be responsible for leading and maintaining our regulatory strategy, writing compliant technical file documentation, and supporting the maintenance and updating of Medical Device Technical files to comply with EU MDR. Additionally, you will lead the delivery of the Post Market Surveillance strategy and reports, and manage multiple regulatory priorities.

Must have:

- Not a typical regulatory mindset – surprise us with your way of (compliant) thinking
- Relevant university degree and >1 year of professional experience, or > 4 years professional experience in regulatory affairs or quality management systems for medical devices
- Experience of working in the healthcare industry (e.g., medical devices, pharmaceutical sector, healthcare authority) and an understanding of medical devices, quality management, clinical trial management, and information security for healthcare data

Desirable:

- Experience with SAMD and agile methodologies
- Knowledge of GDPR and data protection practices to support privacy compliance.
- Knowledge of NHS Compliance standards (DTAC / DSPT)
- FDA experience

Further information about our application and interview process can be found on our website.