



About this role:

Would you like to be an integral part of ensuring patient safety across the European Union?

We currently have an exciting opportunity in our Medical Device Notified Body to join our existing team of Internal Clinicians. Internal Clinicians for UK Notified Bodies must be in current clinical practise, and therefore this role is offered part-time, for 2.5 days per week. This is a home based role in either the UK, Netherlands, France, Spain, Italy or Germany.

Within this role you will:

Contribute essential clinical expertise within your medical specialism to medical device conformity assessments. This includes input into evaluations of:

- equivalence rationales and risk assessments
- appropriateness of clinical claims, indications and contraindications for use, and user information and warnings
- adequacy of endpoints, follow-up and clinical evaluation data
- adequacy of post market clinical follow up provision and follow up
- Mentor BSI technical staff and external clinical experts, to ensure consistency and rigour in clinical data reviews
- Help to develop internal "best practice" guides for clinical evaluation and data requirements within your specialism
- Provide internal and external training in areas of expertise

Key responsibilities of this role are to:

- Develop and maintain an understanding of the regulation of medical devices in the EU, and the position on clinical reviews within it
- Be part of a team undertaking clinical oversight of all clinical evaluation assessments within the Notified Body
- Liaise with subcontracted clinical expertise, and manufacturers' clinical directors if necessary, to ensure any clinical concerns are adequately addressed
- Develop clinical best practise guides and ensure consistency of clinical review for all clinical data reviews being undertaken by BSI
- Provide clinical expertise to clinical evaluations of medical devices in area of clinical competence
- Deliver all services within required timescales and to a high quality
- Maintain client satisfaction whilst continuing to meet BSI's ethical expectations
- Maintain competence in area of clinical expertise by practising as a clinician in line with Competent Authority (MHRA or IGJ).



About BSI:

Do you believe the world deserves excellence?

BSI (British Standards Institution) has over 81,000 clients in 180 countries, and is an organization whose standards inspire excellence across the globe. BSI Medical Devices Notified Body provides rigorous CE and ISO 13485 certification to manufacturers globally. The team apply their knowledge to 3rd party conformity assessment of all types of medical device; active devices, active implantable devices, in vitro diagnostic devices, orthopaedic and dental devices, vascular devices, wound care devices and many others. The team has doubled in size over the past eight years, demonstrating the company's desire to succeed and deliver world beating results. There is exciting opportunities for further growth of the Medical Devices team.

About you;

To be successful in this role you'll be a secondary care evidence-based Interventional Cardiologist who has worked with a variety of medical devices. You'll ideally have experience with analysing clinical data and working with biostatisticians and have experience in clinical trials either as a Principal Investigator or a team member.

What we offer;

This role offers a salary of £100,000 p.a. pro rata (ie £50,000 p.a. based on working 2.5 days per week), 13.5 days annual leave, company-paid private medical insurance, an excellent company-contributed pension scheme, and a wide range of flexible benefits that you can tailor to suit your life-style.

For further information, please contact Lucy Thurmott, Recruitment Advisor- Medical Devices

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