ABINGDON HEALTH

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info@abingdonhealth.com
www.abingdonhealth.com

Regulatory Affairs Specialist – Fixed Term Contract
Location: York, UK

The Regulatory Affairs Specialist will be required to compile accurate technical files in accordance with the requirements of the medical device European *In-Vitro* Diagnostic Regulation (Class II, Class III and potentially CLIA Waiver Applications), to project plan and liaise with regulatory bodies as appropriate. Have a good understanding of quality management systems, such as ISO13485 and 21CFR 820, so as to promote and adhere to the companies Quality procedures and standards, enabling the company to achieve and maintain excellent results.

General Area of responsibility

- Compile materials necessary for new product market clearance, approval, and continuance during product life cycle management that includes (but is not limited to) 510(k)s, supplements, and technical files for CE marking.
- Communicate with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.
- Preparation of additional information or responses as requested by regulatory agencies.
- Advise project teams on subjects such as premarket regulatory requirements, export and labelling requirements, or clinical study compliance issues.
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- Provide technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
- Write clinical protocols to ensure collection of data needed for regulatory submissions.
- Establish and maintain system to track changes in documents submitted to agencies or partners.
- Participate in evaluation of regulatory compliance of document / product / process / test methods.
- Participate in research of regulatory issues and dissemination regulatory information to other departments.
- Establish and maintain close working relationship with the Project Manager(s) and R&D teams to ensure delivery of project in compliance with regulatory guidelines.
- To provide Regulatory support to the QARA Director.

General requirements

The Regulatory Affairs Specialist post is office based, located at our Head Office York, UK, however likely to involve travel to other Abingdon Health sites, located within the UK.

Skills/Competence
Essential

- Excellent understanding of the in-vitro diagnostic market
- Prior experience of preparing FDA (510)K submissions
- Experience in Product Launches and management
- Organised and structured approach to work
- Excellent written and verbal communications skills
- The ability to communicate effectively with a wide range of people
- Attention to detail and good record keeping
- Computer literate (Office packages and email)
- Capable of making decisions under pressure
- Able to work autonomously and also be a team player
- Confident approach to work

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Desirable

- Approximately five years of regulatory experience within the IVD industry
- Strong understanding of the risk environment and management
- Ability to work under pressure, while maintaining high levels of accuracy

Reporting

The position reports to the Quality & Regulatory Affairs Director

Location

York, UK

For information of all opportunities available in the Abingdon Health Group email info@abingdonhealth.com.