Job Description

Regulatory Affairs Officer

Location: Ipswich, Suffolk, United Kingdom
Employment Type: Full-time/Part-time
Salary: Dependent on Age and Experience

About Us:

Deben Diagnostics first started trading in September 2009 and has since seen significant market growth with in the in-vitro diagnostics industry. Operating from its recently expanded offices and distribution centre in Ipswich, Deben Diagnostics supplies and distributes laboratory consumables and test kits worldwide, supplying more than 85 countries particularly to Africa, Europe, the Middle East and the Far East

Job Summary:
Working with the QA Manager to assist in the preparation and maintenance of IVD medical device technical documentation to meet current EU laws under the IVDR, regulation (EC) 2017/746.

Key Responsibilities

- Assessing new and existing products for medical purpose to determine the level of evidence required for technical documentation submission to the Notified Body for product CE marking.
- Compilation of technical evidence to the necessary standards using new or existing methods and processes.
- Planning robust clinical and analytical performance studies, interpreting results and producing effective reports to support IVD medical device intended use and performance claims.
- Liaising with subcontractors to facilitate the effective implementation of clinical and analytical performance studies leading to the collection of complete and compliant data.
- Ongoing maintenance of technical documentation to support continued product safety in the marketplace through integration with associated QMS processes, including PMS, RM, Change Management and CAPA.

Skills and Knowledge

- Working knowledge of, or familiarity with technical documentation to the levels of content and format required for compliance to the IVDR, regulation (EC) 2017/746.
- Understanding of ISO 13485:2016, the principles of quality management, and the ability to integrate with the company's QMS and help maintain its effectiveness.
- Understanding of ISO 14971:2019, the principles of risk management and the importance of its integration throughout the quality management system and in assuring product safety.
- Knowledge of bacteriology and immunology.
- Experience in analytical and clinical study planning and execution.

- Strong technical writing skills with attention to detail and the ability to compose documentation that meets all the requirements laid down in the applicable laws.
- Ability to plan and organise a workload to ensure deadlines are met whilst maintaining a high level of commitment to see long term projects through to completion.
- Proficient computer skills including Microsoft Office suite and willingness to learn new software packages.

Qualifications and Experience

- Degree in Biology or Biochemistry or equivalent relevant qualification and experience.
- Ideally over 3 years of experience in IVD medical device regulatory affairs.

Please email CV with covering letter to

Mr Stephen Hembling - Stephen.hembling@debendiagnostics.co.uk

Recruitment Agencies or telephone applications will not be considered.

Closing date for applications July 1st 2025