Job Advert – Regulatory Manager

ProAxsis are a commercial-stage diagnostics company, with rapidly growing sales of its pipeline of *in vitro* diagnostic products which are based on its highly novel ProteaseTag® technology. The company has a very active product pipeline, with in-house development projects and several in-licensed programmes approaching fruition so is now seeking to recruit an experienced Regulatory Manager to join our growing team.

Summary of Role

The Regulatory Manager will be responsible for obtaining and maintaining appropriate regulatory registrations for ProAxsis' portfolio of diagnostic products.

The ideal candidate will have the following skills & experience:

- Minimum graduate degree, ideally in a life science-related subject.
- Previous practical experience of the CE Mark registration process.
- Clear understanding of the new IVD Regulation (EU) 2017/746.
- Previous experience in managing a QMS in a diagnostics/medical device company
- Ability to understand and summarise clinical data
- Previous involvement in internal/external audits
- Extensive experience of building long-term mutually beneficial partnerships with key customers.
- Having an existing network of key contacts within regulatory sector.

- Specific experience within the respiratory medicine field and/or clinical diagnostics would be highly desirable.
- Experience of regulatory systems outside of Europe would also be desirable.

Core competencies of the ideal candidate will include:

- Very strong interpersonal skills, both face-to-face and via virtual contacts.
- Ability to understand and translate technical scientific data.
- Small company mindset", with willingness to seek innovative solutions to challenges and a "Can Do" attitude.
- Highly effective communicator in all forms of media.

- Strong planning and prioritisation skills.
- Eligibility to work in the UK.

Key Responsibilities

- preparing regulatory submissions for any new products or extensions of existing ones.
- ensuring all documents associated with the company's Quality Management System (QMS) are consistently reviewed and updated.
- ensuring compliance with regulations set by the Medicines and Healthcare Regulatory Agency (MHRA) and all other relevant regulatory bodies for the company's existing portfolio of in vitro diagnostic products.
- planning and overseeing all internal/external audits.
- keeping up to date with changes in regulatory legislation and guidelines.
- outlining requirements for labelling, storage and packaging.
- reading and understanding scientific and legal documents.
- organising and collating information in a variety of formats.
- maintaining familiarity with company product portfolio and pipeline.

This will be a full-time permanent role (Monday-Friday inclusive), with a base salary and additional remuneration commensurate with performance.

The position will be based in Belfast, Northern Ireland. Requests for partial remote working will be considered.

The deadline for applications is 5pm on Friday September 24th 2021.

First round interviews for short-listed applicants will take place shortly after this date.

For further information about the company, please visit www.proaxsis.com

If you believe that you possess the skills and experience to support the company's drive for future growth then please send your CV with a cover letter email entitled "Regulatory Manager" to careers@proaxsis.com

No recruitment agencies please. Due to the high number of applications we receive for job openings, please assume that your application has not been successful if you have not heard from us within 14 days of the submission deadline.