biosignatures

Regulatory Affairs Specialist

Role Description

In this role, your key responsibilities will include:

- The compiling, drafting and preparation of regulatory documents or submissions. Coordinating, preparing, or reviewing regulatory submissions for domestic or international projects
- Communicating with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.
- Interpreting regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures
- Liaising with relevant individuals both inside and outside the company (clinical teams, consultants, regulatory bodies)
- Working on a variety of projects at the same time
- Learning and understanding new areas quickly and comprehensively, supporting internal cross disciplinary teams
- May require travel, domestically and internationally, to meet regulators
- A more detailed role and job description is available by contacting us at jobs@biosignatures.com

Package

Job Type: Full-time
Salary Range: competitive depending on skills, experience and regulatory approval track record
Benefits: including 25 days holiday, pension scheme and flexible working.

Desired Background and Skills

We are looking for another key member of the team to help us deliver our vision of transforming lives by diagnosing disease early. Specifically, we are looking for individuals with many of the following skills and qualifications:

- A bachelor's degree (2:1 or higher) in a life science (biological sciences, biomedical sciences or biochemistry, or a closely related subject) and a strong academic record; appropriate postgraduate qualifications in regulatory affairs will add to the strength of the application
- Experience of preparing, submitting and managing submissions for regulatory approval in the USA (FDA) and Europe (CE)
- A strong work ethic and a solution-focused 'can do' attitude combined with intellectual curiosity and creativity
- A passion for science, patient safety and taking responsibility for the regulatory approval of medical device products
- The ability to work effectively in teams in a fast-paced, dynamic and cutting edge environment

Desirable attributes:

- Post-graduate qualifications in regulatory affairs
- Detailed knowledge of regulatory approvals processes (CE, FDA) and a track record of achieving regulatory approvals
- Some knowledge of regulatory systems in other jurisdictions
- Some knowledge of proteomics and related lab analysis processes (e.g. 2d gel electrophoresis)

How to Apply

Send your CV and anything else you think supports your application to jobs@biosignatures.com and we'll get in touch.

About Biosignatures:

Imagine how many lives we could save if we could diagnose disease long before symptoms became apparent. How many people would live longer, have more productive lives, have a better quality of life and have more time with their loved ones? That's our mission at Biosignatures, we want to transform lives by diagnosing disease early.

Our cross disciplinary team spans clinical trial initiation and management, biobanking, sample processing, biochemistry, proteomics, glycomics, fluorescent image analysis, AI, bioinformatics, biostatistics and diagnostics.