Inceptua operates as a trusted partner for pharma, biotech and healthcare, driving access to treatments for patients in need worldwide. As a highly specialized partner with expert teams across the globe, we use our local insight and global understanding to offer patient- and customer-centric services at all stages of the drug lifecycle: we provide products and services for clinical trials, we facilitate access to pre-approval and unlicensed medicines, and we offer an international commercialization platform for pharmaceutical products.

Our success is based on the motivation, dedication and performance of our people. We strive to go the extra mile to achieve excellence in all our services.

For our office in Windsor (UK), we are seeking a:

Senior Regulatory Associate (m/f)

in our Regulatory Affairs Department for immediate start.

You will be acting as regulatory project lead for specific projects and support internal and external clients requiring regulatory expertise. This includes but is not limited to Medical, Medicines Access, Clinical Trial Services, Clinical Manufacturing Service and Commercial Products (CS).

Responsibilities include, but are not limited to:

- Act as Regulatory Affairs program manager for assigned projects to include submissions, financial tracking, creating and maintenance of all applicable group country applications to ensure the program is compliant
- Provide regulatory expertise for all business units to support the operational delivery of services including but not limited to regulatory advice, guidance , strategic input and oversight of relevant regulatory matters etc...
- Perform daily activities in compliance with established Standard Operating Procedures and ensure that individual responsibilities are carried out in accordance to GXP
- Act as regulatory subject expert for business development opportunities
- Build relationships and successful collaboration with global regulatory bodies and internal and external stakeholders
- Regulatory input into documents to ensure compliance with appropriate regional regulations and guidelines per country including logistics
- Translate legislation and regulation into understandable solutions for input into internal regulatory database
- Support and lead day to day Global Regulatory Intelligence research and maintenance of internal database including information collection, review and catalogue of data
- Remain current on industry, clients, and competitive trends and directions in order to anticipate and identify new business trends, opportunities and challenges
- Provide superior customer service skills by establishing good working relationships with internal customers and external partners

- Vender Management e.g. logistics and Pharmacovigilance service providers
- Establish and prioritize tasks and objectives in order to manage time and resources appropriately
- Make suggestions for improvement that benefit the entire Inceptua Group
- Accomplish individual goals as per requirements determined by the Senior Director - Head of Regulatory Affairs MA &CTS
- Support team training & development of personnel within Inceptua as required to ensure regulatory knowledge is developed.
- Provide basic safety and pharmacovigilance support for Inceptua in collaboration with Senior Director - Head of Regulatory Affairs MA &CTS.

Your profile:

- You hold a Life Science Bachelor's degree
- You have a minimum of 4 years' pharmaceutical or Contract Research Organization (CRO) global clinical trials experience working in a similar role
- Experience of regulatory clinical trial submission document creation and development (for multiple countries). Mainland Europe, Asia and Latin America desirable
- Regulatory Associate Project management experience in a similar role
- Proven track record of working with regulatory agencies
- Ability to translate legislation and regulation into solutions to meet business needs
- Able to develop and maintain global regulatory knowledge
- Experience of working to GXP
- Working knowledge of all MS suite of products (Project, Visio, Power Point, Excel and Word)
- Good working knowledge and experience of working with electronic regulatory systems (e.g. EudraCT, eTMF, EDC, CTMS)

- Effective communication and organizational / time management skills
- Flexibility and adaptability to a rapidly changing regulatory environment
- Enthusiastic individual with superior interpersonal skills and investigative mindset
- Excellent written and oral skills
  Ability to translate legislation and regulation into solutions to meet business needs

This position is full-time, and we offer a competitive salary. Our company is home to employees from various backgrounds that speak a range of languages. If you have a forward-thinking attitude and are ready to go the extra mile with us, we look forward to receiving your application.

Please send your application, including a CV and cover letter in English to: **recruitment@inceptua.com**

Attachments should be in **PDF format** and you should indicate where you found this posting.