Regulatory Affairs (Senior) Manager

Inceptua is a specialty pharmaceutical company and a premium global service partner. Inceptua Services supports pharma and biotech companies with global clinical trial comparator sourcing, packaging, and labelling solutions, pre-approval and medicines access programs and consulting. Inceptua Pharma commercializes and markets orphan and specialty care products and have the expertise and capabilities to supply unlicensed medicines globally.

Inceptua partners with life science companies of all sizes, drawing on over 25 years of industry experience, and has global operations with local offices across Europe, North America, and Asia.

We recognize that investing in talented people creates value for our customers, our employees, our suppliers and the communities in which we live and work. Our success is based on the motivation, dedication and performance of our people. We strive to go the extra mile and achieve excellence in all our services.

Due to a significant increase in new business wins and also to support Inceptua's longer term strategic growth ambitions, we are hiring for the position of **Regulatory Affairs (Senior) Manager**, UK based, for an immediate start.

You will become part of our global Regulatory Affairs Team. You will report to the VP. Global Regulatory Affairs and be responsible for providing regulatory expertise for the Early Access Business Unit. You will work closely together with Inceptua's other team representatives and support functions.

You will act as regulatory project lead for specific projects, support internal and external clients requiring regulatory expertise, and management of the regulatory intelligence database.

Responsibilities include, but are not limited to:

- Provide regulatory experise for the Early Access business unit and occasionally support the Clinical Trial Supply business unit if business requirements dictate.
- Support the operational delivery of services including but not limited to ensuring program compliance, regulatory advice, guidance , strategic input and oversight of relevant regulatory matters, etc.
- Provide regulatory support and guidance to business units, businesses development in collaboration with key functions to scope, sell and deliver early access programmes and consulting projects
- Act as Regulatory Affairs programme manager for assigned programmes and projects; subject matter expert fo business development oportunities
- Attend proposal and bid defence meetings as required to represent the Regulatory Affairs function

- Consult with clients to understand needs and requirements to support development of high quality solutions, providing ongoing internal and external regulatory support and guidance during execution of those solutions
- Responsible for the planning, development and execution of regulatory strategies and plans for assigned programmes
- Regulatory input into documents to ensure compliance with appropriate regional regulations and guidelines per country including logistics
- Country-specific submission planning; document and submission development and maintenance of all group country applications to ensure the programme compliance
- Support the safety requirements for early access, such as client disscussions, monitoring the safety inbox (when requested)
- Build relationships and successful collaborations with global regulatory bodies and internal and external stakeholders
- Manage and maintain the regulatory repository/intellignce database(s) that serve company business
- Support day to day Global Regulatory Intelligence research and maintenance of intenal database including information collection, review and catalogue of data; communicate any impact to business
- Scan regulatory landscape to idenfity new or revised country specific legislation and regulations for any changes; translate legislation and regulations for input into regulatry repository/regulary database(s)
- Remain current on industry, clients, and competitive trends and directions in order to anticipate and identify new business trends, opportunities and challenges

Your profile:

- You hold a University degree in natural sciences (e.g., Biology, Biochemistry, Pharmacy) or Quality Management
- You have a minimum of 3-5 years proven regulatory experience within the pharmaceutical Industry (pharma company or CRO/Service Partner)
- You have an extensive knowledge of EU Directive, the US CFR and GMP/GDP associated regulations
- You are business fluent in English
- You have a pragmatic mind-set
- You have an overall company view and mindset
- You are a proactive team player

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 in English, including a covering letter, to **recruitment@inceptua.com**
Attachments must be in PDF format.