Product Development and Regulatory Consultant (Full time)

Clinical Network Services (CNS) is seeking a **Product Development and Regulatory Consultant** to join our ***BioDesk*** team in the UK in a full time position.

CNS is an integrated service group, focused on clinical product development, which create value for biotechnology companies by progressing early stage products through phase 1 & 2 clinical trials or to the marketplace sooner. BioDesk (a division of CNS) is a global product development and regulatory affairs consultancy which offer CMC/manufacturing, toxicology, clinical/medical and regulatory affairs expert consulting services.

CNS is headquartered in Brisbane, Australia with offices in New Zealand, the USA (Washington DC) and the UK. In the UK we are currently located in St Albans, Hertfordshire, but moving to Bishop's Stortford area at the end of October.

Your main responsibilities will be to:

- Provide technical and strategic product development and regulatory advice on a wide range of medicinal product types
- Maintain knowledge of relevant guidance (in particular European focused) and provide considered advice on key requirements
- Assess and analyse scientific data
- Prepare gap analyses and product development plans, and define regulatory strategy
- Prepare and review documents for regulatory submissions and procedures, and provide oversight to ensure that documents are in compliance with applicable regulatory requirements
- Engage in regulatory authority meetings, on behalf of or in support of our clients
- Interact directly with clients, and manage delivery of client projects

You will have:

- A high scientific calibre with a life science focused BSc (or equivalent), and a higher degree (e.g. a life science focused MSc or PhD)
- At least 2 years practical/technical experience in product development, preferably from working within SME biotech
- A strong ability to quickly assimilate, interpret and summarise scientific information
- Excellent written and verbal communication skills
- Excellent project management skills
- A good understanding of drug development
- Ability to work in a proactive and autonomous manner as well as being part of a team
- Good organisational skills with a high level of attention to detail
- High level of computer literacy and competency in MS Office programs
- General awareness of regulatory affairs is sufficient but having a more detailed insight into the regulatory environment for medicinal products would be an advantage
- Previous consulting experience would be advantageous but not a prerequisite
- Willingness to work flexible hours and (inter)national travel for short periods and sometimes at short notice

Our offer:

- A challenging and stimulating position for a dynamic and competent scientist, wanting to contribute to a growing business and a rapidly expanding team
- Coaching and mentoring to support your continuous learning, tailored to your individual needs
- Support your professional development within a highly professional, internationally recognised dynamic team
- A unique working environment driven by strong company values and a very high level of employee engagement across the international organisation
- A salary that is commensurate with your experience

In order to apply for this position please send a detailed cover letter and CV to Mr. Paul Cronin at paul.cronin@clinical.net.au

Application closing date 12th September 2017