**Regulatory Affairs Officer**

**Description of Position**

This is a perfect opportunity for a new science graduate with a keen interest in working in pharmaceutical industry regulatory affairs or a science graduate with some regulatory affairs experience looking for a new challenge.

The position is a fixed term, 1 year contract within the Development Regulatory Affairs Unit, part of Orion’s Proprietary Products, R&D function. Here you will support regulatory activities related to Orion’s propriety products development portfolio. Your responsibilities include the following activities:

* Assist Regulatory Affairs Managers in developing regulatory strategy for proprietary products in development
* Assisting Regulatory Affairs Managers authoring regulatory documentation in support of regulatory activities including clinical trial authorisation applications (CTAA), scientific advice and marketing authorisations applications (MAA)
* Collecting, collating, and check scientific data for submission to regulatory competent authorities
* Making and maintaining CTAA for clinical trials undertaken by Orion
* Liaising with regulatory competent authorities and CROs
* Reviewing documentation generated by CROs in relation to Orion sponsored clinical trials or Orion’s MAA
* Ensuring required MAA documentation, is available in accordance with agreed timelines and is of the highest quality
* Identifying regulatory risks and formulating risk mitigation plans
* Ensuring you keep abreast of national and international regulatory legislation and guidelines
* Interpreting legislation and guidelines as they relate to Orion’s R&D activities and products in development
* Supporting Regulatory Affairs Managers in other tasks as required.

This position reports to the Director, Development Regulatory Affairs. The location of this position is either Nottingham, UK or Espoo, Finland. Whilst the position is a fixed term contract, there is a possibility that it could lead to the successful candidate being offered a full-time permanent position within Orion, once the fixed term ends.

**Description of Unit**

The Development Regulatory Affairs Unit is part of Orion’s R&D function responsible for developing proprietary products. The Unit is a crucial and integral part of drug development within Orion. The Unit not only provides strategic regulatory guidance to the drug development process, but also operational support and is the pivotal link between Orion and regulatory competent authorities globally. Members of Orion’s Development Regulatory Affairs Unit combine their knowledge of scientific, legal and commercial awareness to ensure products developed meet the required legislation for clinical trials and market authorisation.

**Requirements**

To be a successful in this role, you will possess:

* a pharmacy or life science degree
* a demonstrated interest in working in the field of pharmaceutical Regulatory Affairs or previous experience within Regulatory Affairs in a pharmaceutical company or CRO
* flexible attitude and willingness to learn
* ability to work effectively as part of a culturally diverse team
* ability to critically analyse regulatory guidelines and scientific data to formulate regulatory strategy
* a ‘can-do’ attitude
* creative and innovative thinking to help develop regulatory solutions to arising issues
* high quality standards and attention to detail
* confident and articulate communication skills (both written and verbal), with the ability to convey and present highly complex information to others clearly and logically
* ability to organise your own work load, be proactive and juggle a range of tasks/ issues simultaneously
* ability to work to strict and tight deadlines

**Salary**

£23k-£25k

**Closing date for cv’s**

20th August 2021 - **Please send cv’s to: Debbie.Payne@orionpharma.com**

**Interviews**

w/c 6th September 2021

**Start date**

27th September 2021