**Clinical Risk Management Associate**

**Description of Position**

This is a perfect opportunity for a new science graduate with a keen interest in working in pharmaceutical industry Risk Based Quality Management (RBQM) or a science graduate with some risk management experience looking for a new challenge.

The position is a fixed term, 2 year contract within the Clinical Operations, Global Development Unit, part of Orion’s Proprietary Products, R&D function. Here you will support Risk Management activities related to Orion’s propriety products development portfolio. In addition to supporting RBQM activities, the successful candidate will also support the Senior Clinical Risk Manager in Randomisation and Trial Supply Management (RTSM – Interactive Response Technology systems) activities. The responsibilities associated with this position include the following activities:

* Assist Senior Clinical Risk Manager in
  + developing RBQM strategy for clinical trials in development
  + conducting Risk Assessments on clinical trials and authoring risk management documentation in support of RBQM activities
  + performing scheduled Risk Reviews on accumulating clinical data, including review of Key Risk Indicators (KRI) and Quality Tolerance limits (QTL), on ongoing clinical programs.
* Collect and collate results of Risk Reviews to assist the Senior Clinical Risk Manager in the conduct of monthly Risk Management meeting with stakeholders
* Maintain risk management documentation in support of RBQM activities
* Liaise with internal Clinical Study Team and Clinical Research Organisations (CRO) in support of RBQM activities
* Review documentation generated by CROs in relation to Risk Management for Orion sponsored clinical trials
* Ensure required RBQM documentation is available in accordance with agreed timelines and is of the highest quality
* Ensure you keep abreast of regulatory legislation and guidelines, especially ICH GCP E6 and E8
* Interpret legislation and guidelines as they relate to RBQM and support the Senior Clinical Risk Manager in developing/updating operational processes to ensure Orion is compliant with legislation and guidelines
* Support the Senior Clinical Risk Manager in developing and maintaining RTSM system for upcoming and ongoing clinical trials
* Support Senior Clinical Risk Manager in other tasks as required.

This position reports to the Senior Clinical Risk Manager. The location of this position is Nottingham, UK.

**Description of Unit**

Clinical Operations, Global Development Unit is part of Orion’s R&D function responsible for the delivery of Orion’s clinical trials related to the development of proprietary products. The Unit is a crucial and integral part of drug development within Orion. The Unit’s main role is to design, plan and physically perform the clinical trials during the four phases of development i.e. Phases I-IV. The Unit ensures that all clinical trials carried out by Orion are compliant with current regulatory/guideline applicable to the pharma industry, and liaises with other units in Research and Development to ensure the successful execution of the clinical trials, and marketing authorisations for Orion’s proprietary medicines.

**Requirements**

The successful candidate in this role, will possess:

* A pharmacy or life science degree
* Demonstrated interest in working in the field of pharmaceutical RBQM or previous risk management / centralized monitoring experience in a pharmaceutical company or CRO
* Critical thinking skills with the ability to independently solve problems with data
* Excellent organizational and time management skills with the ability to work to tight deadlines to meet objectives and operate effectively with multiple competing priorities to achieve quality results
* Ability to critically analyse and aggregate data to formulate comprehensive risk review outputs
* Confident and articulate communication skills (both written and verbal), with the ability to convey and present highly complex information to others clearly and logically
* Demonstrated flexibility, adaptability and willingness to learn
* Innovative thinking to help develop and improve RBQM processes
* Excellent team working skills including the ability to work as part of a multidisciplinary team environment
* Motivation and an innovative approach to the job within a changing working environment
* High quality standards and attention to detail
* Basic knowledge of statistics and metric development
* Ideally, knowledge of RTSM and software development & management (not mandatory)

**Salary**

£30k

**Closing date for cv’s** (to: [Debbie.payne@orionpharma.com](mailto:Debbie.payne@orionpharma.com) )

11th February 2022

**Interviews**

w/c 28th February 2022

**Start date**

18th April 2022