Position:	**PV & MA Officer**
Hours:	**37 (09:00 - 17:30 Mon – Thurs 09:00 – 17:00 Fri)**
Base Salary:	**Starting from £35,000** (open to full early negotiation for right candidate)
Benefits:	**Private Health Insurance * Life Assurance * Contributory Pension Scheme**
Location:	**Egham, Surrey, UK, (M25, J11/J13, Surrey/Middlesex borders).**

About Us

Essential Pharma is part of a larger group of companies whose aim is to ensure the sustainable supply of low volume, difficult to manufacture but clinically well-established pharmaceutical products to patients who need them. These branded and generic medicines form an essential part of the pharmacopeia and represent many therapeutic areas. We operate in over 30 countries, including in the UK, EU, Asia and New Zealand, supplying a portfolio of over 150 essential therapies across 9 therapeutic areas. Our products are manufactured to the highest regulatory standards at 8 sites in the EU and 2 sites in the USA.

The Role

As the Medical Information and Pharmacovigilance Officer, support, expertise and capacity to the Operations team by contributing to activities in both Pharmacovigilance (PV) and Medical Affairs (MA). In the former, the position contributes to assuring that the activities needed for the company to fulfil the legal requirements for pharmacovigilance (in the UK). In the latter, the role performs a range of tasks including Medical Information provision and supporting the fulfilment of various responsibilities of the Marketing Authorisation Holder for the product portfolio, working with Regulatory Affairs, Quality Assurance and external contractors.

The nature of the functions means that day-to-day activities are not predictable. Priorities are determined through interaction and collaboration with other colleagues fulfilling similar functions, so that operations are managed equitably, efficiently and in the best interests of the business.

For PV services specifically, the position reports to the EU Qualified Person for Pharmacovigilance (QPPV). Otherwise, operationally the position holder's line manager is the COO.

Key Duties and Responsibilities

Your main tasks and responsibilities will include:

Pharmacovigilance

- Forward spontaneous Individual Case Safety Reports (ICSRs) to the PV team in accordance with the company's current MI SOPs
- Collaborate with the QPPV, Medical Advisor and other subject matter experts on various aspects of Pharmacovigilance upon request
- Contribute to the documentation needed for
    - Periodic Safety Update Reports (PSURs) for submission to Competent Authorities

  - Risk Management Plans (RMPs) for submission to CAs
  - Safety Data Exchange Agreements (SDEA) and their obligations to third parties for applicable products
  - PV Agreements or PV-related clauses in other agreements
  - CAPAs, deviations and risk assessments
  - Monthly reconciliation of MI/PV/PQC to check every patient safety-related MI/PQC case has been escalated to assure PV Compliance
  - Pharmacovigilance data and other relevant statistics for the compiling of compliance reports
- Participate in audits and inspections
- Contribute to the preparation and delivery of PV-related induction training and refresher training to non-PV staff according to the frequency required by SOPs

Medical Affairs

- Respond to external and internal medical information (MI) enquiries in relation to the safe and effective use of all products marketed by the company within the required timelines
- Handle escalated enquiries from external Medical Information vendors and internal stakeholders, and peer review those handled by colleagues
- Periodic & ad hoc update of MI standard responses as part of best practice, creating and reviewing as appropriate
- Create and maintain scientifically accurate and balanced Medical Information documents
- Conduct literature searches to identify data to respond to more complex MI enquiries
- Support in reviewing and processing of certificates of analysis for received product batches
- Product Information maintenance including updates to SmPC/PIL/MI Standard Response in MI database upon Regulatory Affairs team's communication
- Review and support updates to SOPs in functional area to ensure that systems and processes are in a permanent state of inspection readiness

Other Activities

- The role is also required to extend the capacity for managing, processing and resolving Product Quality Complaints through strong engagement with colleagues in Quality Assurance
- Review and process batch certificates and product samples to support RPi batch release

Your Profile

You will have:

Qualifications

- Degree in Pharmacy, Pharmacology, Biochemistry or other related life science subject

Experience

- Demonstrable experience in Pharmacovigilance and/or Medical Affairs

Competencies

- Strong agile thinker who can adapt to situations of high-speed change
- Good attention to detail
- Good knowledge of scientific and medical terminology
- Strong IT skills especially in MS office applications
- Ability to write clear, coherent and compelling reports
- Possesses excellent verbal and written communication skills (must be fluent in English)
- Experience of producing high quality work and be detail orientated
- Demonstrates integrity and high ethical standards
- Demonstrates a growth mindset and willingness to learn
- Works effectively as part of team with strong collaboration
- Proven ability to prioritise work to meet required deadlines
- Possesses a can-do attitude and committed to achieving success without compromising quality of work

To apply

Please send your CV to **careers@essentialpharmagroup.com** along with your current salary and salary expectations.