Position:	**Manager, Regulatory**
Hours:	**37 (09:00 - 17:30 Mon – Thurs 09:00 – 17:00 Fri)**
Base Salary:	**£40,000 - £48,000**
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 20 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 Manager, Regulatory, you will support all regulatory aspects of the product portfolio ensuring compliance with all applicable local and regional legislation. The Operations department carries out a range of functions to support the responsibilities of the Marketing Authorisation Holder liaising both internally with other functions and with our external contractors.

Key Duties and Responsibilities

Your main tasks and responsibilities will include:

- Preparation and/or review of regulatory applications including change of ownership, variations, renewals, new Marketing Authorisation applications in EU and UK territories.
- Support regulatory approval and maintenance of products in global locations in conjunction with local partners or licence holders.
- Prepare and/or review product information text.
- Implementation of product artwork.
- Review of product regulatory compliance.
- File regulatory documentation internally, maintain comprehensive product files.
- Advise on Change Requests for Regulatory function.
- Initiate Change Requests for regulatory changes.
- Communicate regulatory changes to contract manufacturers and other interested parties both prior to and following update of the Marketing Authorisation.
- Discuss and collaborate with Pharmacovigilance and Medical Affairs departments regarding safety/core datasheet updates initiated by health authorities or Safety Data Exchange partners.
- Participate in project teams concerning technical transfers or technical changes to products
- Review potential acquisition proposals and contribute to due diligence

- Participate in the integration team for selected acquired products.
- Ensure integration of the acquired product regulatory files into the internal filing system.
- Assist where required with responses to medical information enquiries and product complaints.
- Assist and lead where required in the development and maintenance of standard operating procedures and local working practices.
- Advise and support with the regulatory aspects of clinical trials.
- Advise on Regulatory aspects of new and emerging legislation, making every effort to keep up to date with current requirements and responsibilities of the Marketing Authorisation holder.

Your Profile

You will have:

Qualifications

- Pharmacy, Chemistry, Medical Science, or life sciences degree.

Experience

- Regulatory Affairs (Pharmaceutical)
- Medical Devices Regulation
- UK/European/multinational

Competencies

- Strong agile thinker who can adapt to situations of high-speed change
- Good attention to detail
- Problem solver who can work through complex issues
- Demonstrate a Growth mindset and willingness to learn
- Demonstrate integrity and high ethical standards
- Demonstrate working effectively as part of team with strong collaboration
- Demonstrate a willingness to achieve goals together and respect the view of others
- Results orientated and accountable for actions

To apply

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