Blue Reg Group is a consultancy organization specialized in Development, Regulatory Affairs, Pharmacovigilance, Market Access and Quality Management for the Pharmaceutical Industry.

Located in Paris, Sophia-Antipolis and London, we provide strategic advice and hands-on outsourcing solutions to life science companies through the entire lifecycle of their products.

We are currently seeking a:

Senior Consultant, Regulatory Affairs

Within the Global Operations Unit, you actively provide tailored regulatory consultancy services for a range of clients, from ad hoc advice to long term partnership:

Key duties and responsibilities are summarized below

You are a source of expertise in the registration and post-licensing activities of pharmaceutical products or other health products:

- Registration (e.g. coordination of EU procedures, responses to questions, experience with export countries).
- Post MAA (e.g. preparation and submission of variations, advice on classification and documentation required, MA holder transfers, renewals, PSUSA).
- Supports the regulatory local launch activities at global level and early access program (set up the regulatory launch strategy, coordinates local partners, compiles local requirements).
- Global regulatory promotional materials review & validation: reviews and validates promotional materials from a regulatory point of view as per EFPIA/IFPIA guidelines, coordinates partners.
- Writing of regulatory documents.
- Interaction with agencies and partners.
- Conducts due diligence on the regulatory part of dossier/company.
- If possible, you are also experienced in development and regulatory strategy (e.g. scientific Advice, ODD, PIP, CTA).

You ensure high quality and on time delivery to clients to maintain client satisfaction.

As part of your activities, you bring your expertise to all Blue Reg teams and are required to contribute to various projects.

Experience

- A least 7 to 10 years' experience in the pharmaceutical industry, broadly based Regulatory Affairs experience, including a successful track record in the registration and maintenance of pharmaceutical products within Europe and/or at export.
- Experience in consultancy would be a plus.

Education and skills

- Pharmacist / Engineer / Life Sciences Graduate.
- English as native language or fluent in English (written and spoken).
- Excellent verbal and written communication skills.
- Good organizational skills with ability to work on multi-projects in a multi-cultural and matrix environment.
- a global environment.
- Established relationships and proven negotiation skills with management, colleagues

and/or regulators.

- Decisive and proactive, with “small company” hands-on, can-do style and attitude.
- Good analytical skills.
- Team spirit.

This position is based in UK (High Wycombe). Can also be partly home based.

Please send a copy of your CV and a cover letter with mention in object to nadia.boehringer@pharma-blue.com with mention in object : « *Application Senior Consultant, Regulatory Affairs - Name, Forename* »