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:

Junior Consultant, Regulatory Affairs

Within the Global Operating 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 have a short experience (internship, short term contract, …) in the registration and post-licensing activities of pharmaceutical products or other health products:

- Support the 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

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

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

Experience

- At least 6 months initial regulatory experience gained through internship in pharmaceutical/biotechnical companies and/or regulatory authorities
- Experience in consultancy would be a plus.

Education and skills

- Ideally a Pharmacist / Engineer / Life Sciences Graduate or equivalent qualification as a minimum.
- 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
- Good analytical skills.
- Team spirit.

This position can be based in UK (High Wycombe) or in France (Paris or Sophia-Antipolis). Can also be partly home based.

Please send a copy of your CV and a cover letter with mention in object to xxxxxxxxxxxxx
with mention in object : « *Application Junior Consultant, Regulatory Affairs - Name, Forename* »