



BlueReg Group is a consultancy company specialized in Development, Regulatory Affairs, quality management and Pharmacovigilance for the Pharmaceutical Industry.

Based in Paris, Sophia Antipolis and London, BlueReg Group has over 100 clients ranging from large multinationals to small start-up companies, from innovators to generic companies. BlueReg was founded in 2011 and, since then, has experienced significant year-on-year growth. In the context of its continued growth, BlueReg Europe is currently seeking a:

## **Senior Consultant, Scientific Writing**

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

### **Key duties and responsibilities:**

With minimum senior management supervision, you plan and implement the writing strategy of regulatory documents for drug development, registration and maintenance activities for Europe and US.

You achieve all the activities linked to the scientific support and writing of regulatory documents, especially:

- Liaise with authors and clients
- Advice and support on regulatory and scientific aspects to clients
- Lead process of document reviews
- Writing of scientific and regulatory documents such as:
  - Briefing documents for scientific advice (EU, US)
  - Orphan Drug Designation request (ODD)
  - Paediatric Investigation Plan (PIP)/ Paediatric Study Plan (PSP)
  - Investigational Medicinal Product Dossier (IMPD)/ Investigational New Drug (IND)
  - Investigator's Brochure (IB)
  - Clinical Study Report (CSR)
  - CTD modules for MAA (or variations) : Non Clinical and Clinical Summaries and Overviews, Risk Management Plan
  - Responses to Agencies questions

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

### **Education and skills:**

- Pharmacist / Engineer / Life Sciences Graduate
- Between 5 to 10 years' experience in Scientific Writing
- 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 multiple projects or activities in parallel
- Good analytical skills
- Team spirit

This position is based in Sophia Antipolis (South of France) or Paris or London (UK). Can also be home based.

Please send a copy of your CV and a cover letter to [rh@blue-reg.com](mailto:rh@blue-reg.com) and [cance.peggy@blue-reg.com](mailto:cance.peggy@blue-reg.com)