JOB DESCRIPTION

Director Scientific Writing Drugs & Biologics

BlueReg is a consultancy company specialized in Regulatory Affairs in development/registration & maintenance, quality management, pharmaceutical development, writing, publishing and Pharmacovigilance for the Pharmaceutical Industry.
Based in Paris, Sophia Antipolis and London, BlueReg 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 **Director, Scientific Writing Drugs & Biologics.**

This position is based in Sophia Antipolis (South of France) or Paris or London High Wycombe (UK

SUMMARY

Manages and Leads the Global Scientific Writing Team.
Acts as Senior Expert in Regulatory Writing and provides its expertise to customers and to all BlueReg collaborators.
Is a source of Regulatory Writing expertise in the global development, registration and maintenance of pharmaceutical products (drugs and biologics) or other Health care products (medical devices/cosmetics/herbals).
Develops and maintains a network with the professional associations, regulatory agencies and clients.
Contributes to the effective functioning and to the business growth of BlueReg in general and BlueReg Europe in particular

KEY DUTIES AND RESPONSIBILITIES:

Client Activities

- Manages and leads the Global Scientific Writing Team which provides a full range of consulting services (review and write or coordinate the document production) in clinical, nonclinical, CMC, pharmacovigilance & safety areas for all kind of Health products.
- Ensures that activities within the Scientific Writing team are planned and implemented and projects delivered on time and to a high quality
- Contributes in close relation with Business Development to the preparation of the financial quotation proposals and develops/proposes offer related to scientific writing.
- As Director Scientific Writing Drugs & Biologics, ensures that direct collaborator's workload is controlled and align usage of 3rd party partner(s) accordingly.
- Leads activities such as:
    - Development, registration and post-submission activities: supervises writing of CMC, nonclinical, clinical, PV CTD modules (CSR, RMP, PSURs, Module 2 for MAA/IND), IMPD, IB, responses to questions, audit, briefing package for pre-submission meeting/ODD/PIP, PIP dossier, or any other scientific documents related to Health products development, registration, maintenance or any other post-market activities

    - Provides writing support for clinical and nonclinical study designs (protocol).
    - May also support client for writing of publications and abstracts for external communication purposes
- Review and/or write assigned Regulatory documents on her/his own assigned documents
- Acts as Project Manager on her/his own assigned projects

- Reviews deliverables prepared by other consultants or partners.
- Interacts professionally at multiple levels within client organisations.

Organizational Effectiveness

- Manages permanent and contingent headcount to ensure that appropriately qualified and experienced staff are available to address the strategic and operational objectives of the group.
- Ensures Global Scientific writing group continuous evolution is aligned with existing and emergent guidances .
- Ensures appropriate training and personal development of Scientific Writing collaborators.
- Develops and maintains a Performance Culture and ensure continuous improvement of BlueReg processes.

Business Development

- Identify and contribute to acquisition of new potential projects or clients according to plans established with Business Development
- Accompany business development team when visiting clients/prospects to present Scientific writing services
- Develops new offers on writing support & medical expertise by assessing emergent guidances and current markets & competitors and participates to the development of specific business plans related to her/his activities.

Knowledge Management

- Acts to develop and maintain regulatory skills and knowledge necessary to ensure effective support to clients.

BLUE-REG Activities

- Develops and maintains personal contacts with regulatory agencies or professional associations to build confidence in and enhance the reputation of BlueReg.
- Completes basic job-related responsibilities e.g. maintenance of personal training record, timesheets, project archiving.

EDUCATION AND EXPERIENCE

- Pharmacist, Medical Doctor or Life Sciences Graduate,
- A least 15 years of experience in the pharmaceutical industry, with a minimum of 8 years in Regulatory Writing at the international level
- Sound knowledge of ICH & non-ICH pharmaceutical regulations and guidelines.
- Experienced in cross-functional project teams.

ESSENTIAL SKILLS AND ABILITIES

- Excellent written and verbal communication skills across multiple levels of an organisation.
- Established relationships and proven negotiation skills with management, colleagues and regulators.
- Proven ability to work across a wide spectrum of activities.
- Good organisational skills with ability to work on multiple projects or activities in parallel.
- Good analytical skills.
- Excellent scientific writing skills.
- Very good level in English (Native English speaker or fluent in English).

This position is based in Sophia Antipolis (South of France) or Paris or London High Wycombe (UK)
Please send a copy of your CV and a cover letter to contact@blue-reg.com>