**Category (check the box that applies):**
☒ **Regulatory & Pharmaceutical Affairs**
☐ **Pharmacovigilance & Safety**
☐ **Consulting & General Services**

**REGULATORY AFFAIRS MANAGER deputy of Hub leader**
**LOCATION: GERMANY Haan- RA Hub Central EU**
**CONTRACT: Permanent**

ProductLife Group is the European industry-leading specialist service provider for the Life Sciences industry, focused on delivering high quality professional services in the areas of Regulatory, Safety, Quality, Process alignment and Medical services. All ProductLife Group's services are targeting support for comprehensive compliance and safety throughout the product life cycle, therefore enabling continuity and productivity of product development and subsequent processes.

As a result of the deployment of a new project we are now seeking a **Regulatory Affairs Manager deputy of Hub leader** responsible for ensuring delivery of regulatory services by the RA international platform based in Suresnes

**Primary Responsibilities**

Under the monitoring of the **Hub leader** your missions are:

- Manage or supervise the compilation of regulatory files respecting national requirements
- Obtain regulatory approvals.
- Provide regulatory advice to project teams to ensure the inclusion of regulatory concerns in relevant data planning and production to achieve the project objectives.
- Provide regulatory support to clients and associates.
- Liaising with regulatory authorities as required.
- To review the format and content of the texts related to packaging, summaries of product characteristics, labeling and records.
- Review the tasks, provide support and assist in charge of Regulatory Affairs and Regulatory affairs partners.
- Assist Platform managers / or regulatory Hub consultants Senior Regulatory Affairs before sales
- Provide technical support before sales
- Ensure adequate technical description of the proposals and provide support for sales in costing
- Ensures that invoicing is correctly set. Validate invoices.
- Controls data entry of the Platform/Hub staff in PLG tools. Ensures KPI, metrics for all regulatory services supplied by the platform/the hub are adequately measured and reach or exceed defined targets

**Candidate profile**

- **Education** Life science related field (Pharmacist etc…)

- **Experience 8 years minimum** of professional experience required in a similar position in regulatory affairs, **QP function and QA/ CMC project management.**

**Key skills**

- Expert in **EU and German registration**
- **QP, QA and CMC experience**
- Excellent organizational and interpersonal skills
- Ability to coordinate, lead and motivate a team
- You are **fluent in German (spoken and written)** and English for daily contacts with local and worldwide partners.

**Core competences**

- Project management skills
- Rigorous and Pragmatic
- Customer- and Quality focus
- Result driven , accurate
- Problem solving capabilities

Full training will be provided, and we encourage our staff to attend external courses as appropriate and to join professional organisations.

There will be opportunities for advancement within the company or the wider group for motivated candidates, who have the ambition and potential for growth in our dynamic and international organisation.

**Benefits**

- Competitive salary package
- Training and development
- International and growing company
- Dynamic environment

Please email a Curriculum Vitae and cover letter to recruitment@productlife-group.com.