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

Regulatory Affairs Manager Junior
Germany
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 increased workload, we are now seeking a Regulatory Affairs Manager Junior responsible for allocated activities or projects within the Regulatory Affairs function.

Primary Responsibilities

- Ensure delivery of regulatory activities performed on the RA Platform/the Hub. Regulatory activities include pre licensing activities, new registration (sites and medicinal products), post licensing regulatory submissions, interaction with health authorities on behalf of PLG customers
- Compile, or supervise the compilation of regulatory dossiers in accordance with national requirements.
- Gain regulatory authority approval.
- Provide on-going regulatory advice to project teams to ensure regulatory concerns are planned and accounted for and the relevant data are generated to meet project objectives.
- Provide regulatory support to clients and associate companies.
- Liaise with external regulatory authorities as required.
- Provide format and contents review of packaging texts, Summary of Product Characteristics, Patient Information Leaflets and labelling.
- Assist the RA Platform / Hub Leader or a Senior RA consultant in presales:
    - Ensure providing technical support to presales
    - Ensure adequate technical description of the proposals and support sales for quotation evaluation
- Control that invoicing is correctly set.
- Contribute to data entry in PLG tools enabling measurements and measure KPI/metrics for regulatory services supplied by the platform/hub

Other

- To produce and review SOPs relating to the Regulatory Affairs function.
- To participate in training as required
- To provide in-house training as required for staff in the Regulatory Affairs group.
- To contribute to the production of client documents and reports
- To support the Pharmacovigilance group in the production of Regulatory Authority and Ethics Committee documentation.
- To liaise with other group companies on regulatory issues and to provide support for their activities in the regulatory field.
- Contribute to follow up of the quality of service of regulatory partners working with the Platform/the Hub.
- To represent PLG in regulatory associations, events and congress
- To comply with the company's policies and procedures to meet statutory, quality and business requirements within the overall strategy and objectives.

Principal internal and external contacts

Internal

- Country General Manager
- Head of Delivery
- Head of Function
- Platform/Hub Leader
- Regulatory Colleagues
- Pharmacovigilance Group
- Quality Assurance
- IT

Candidate profile

- **Education and Experience**
- Bachelor's or higher graduate degree in a science related field, or equivalent experience This experience should include a proven understanding of the regulatory process and experience in leading a project to successful completion.
- Excellent organisational and interpersonal skills
- Ability to co-ordinate, manage and motivate a team
- Process orientated with good attention to detail
- Effective oral and written communication skills
- Good computer skills and the ability to learn appropriate software
- Good understanding of regulatory tracking database software, eDMS, MS Word, MS Excel

- Good English language and grammar skills (written and verbal fluency)
- Good knowledge of regulatory procedures
- Minimum **4 year experience** in a regulatory affairs department required

Key skills

- Excellent organisational skills
- Ability to work well within a team
- Process orientated with good attention to detail
- Effective oral and written communication skills
- Fluent written and spoken German and English language

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.