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

Regulatory Manager and Information Officer
Germany
Fixed Term (20 hours/week per activity)

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 a new project we are now seeking a Regulatory Manager and Information Officer Responsible for all necessary regulatory activities for the maintenance of an assigned portfolio of German marking authorisations. This comprises product-specific regulatory aspects as well as operational activities, including submissions in due time. The major accountabilities (but not limited to) are as follows:

Manager Regulatory Affairs

Full regulatory maintenance of an assigned portfolio of German marketing authorisations. Requires pharmaceutical knowledge about the nature and mode of action of medicinal products.

Additional role as regulatory expert re. labelling and artworks

Information officer

Externally announced information officer with experience in accordance with § 74a AMG - labelling, package leaflet and professional information (Fachinformation) provides scientific information on the medicinal products and any pharmaceutical aspects.

Primary Responsibilities

- Preparation and submission of national and European variations (Type IA, IB and II) as well as renewal applications with Germany as CMS and RMS, respectively.
- Preparation and submission of national Marketing Authorisation applications by national, MRP or DCP.
- Local contact for centrally approved MAs.
- Contact partner for global Regulatory Affairs department and/ or licensors RA department for the assigned product portfolio.
- Management of national re-registration procedures including suit procedures at the German court.
- Project coordination concerning filing objections against the local authorities.

- Preparation of statements in response to deficiency letters regarding the formal pharmaceutical, medical and quality aspects.
- Review of quality documentation (modules 2.3 and 3)
- Review of medical and clinical expert reports.
- Coordinate input from other global and local departments required from regulatory activities
- Participate in cross-departmental project teams as regulatory representative, as needed; provide regulatory advice to other stakeholders.
- Preparation, update and translation of national PI-texts in accordance to European templates, CCDS and recommendations of the national authorities.
- Review and release of packaging print materials and printed SmPCs.
- Follow European regulatory legislation and guidelines, analyse consequences and adapt regulatory strategies and processes in time.
- Inform and advise colleagues from other departments of the quality, efficacy and safety of medicinal products.
- Preparation of pharmaceutical information about medicinal products (especially biologicals)
- Providing pharmaceutical information on the application of biological products.
- Collection, processing and distribution of pharmaceutical data (e.g. by using databases)
- Benefit assessment of pharmaceuticals in accordance with the German Social Code ("Nutzendossier"): providing regulatory and pharmaceutical information and acting as member of the "Nutzendossier" team in the context of the dossier submission in accordance with SGB V; inclusive preparation and review of parts of the dossier by using his/her pharmacologic and regulatory expert knowledge.
- Training and guidance of student apprentices of pharmacy ("Pharmaziepraktikant") and trainees.

Specifically for the role as expert regarding labelling and artworks:
-Pilot and/or master user for new labelling and/or artwork systems and processes
-Author of corresponding local SOPs
-Primary local contact partner for other local/global departments

The information officer is responsible for the tasks of proving scientific information on medicinal products in accordance with §74a AMG.

The information officer shall, In particular, be responsible for:
-ensuring compliance with the prohibitions to prevent deception (contained in section 8 sub-section 1 number 2 AMG),
-Ensuring that the labelling, the package leaflets and the professional information (Fachinformation) correspond with the content of the marketing authorisation.
-Controlling the labelling, the package leaflets and the professional information (Fachinformation) of medicinal products by using his/her expert knowledge about pharmaceutical aspects and current legislation.
- The final release of all packaging materials and Fachinformationen training and guidance of student apprentices of pharmacy ("Pharmaziepraktikant") and trainees.

Candidate profile

- **Education**
  Master's degree in pharmacy
  Pharmaceutical degree or proven relevant experience

- **Experience**
  Minimum of 2-3 years professional experience in pharmaceutical industry, preferably in regulatory affairs

Problem solving
Proactively identify issues and problems that threaten regulatory objectives.
Proactively provide suggestions for resolution of issues.

Key skills
- pharmaceutical knowledge
- Project management skills and ability to adapt to rapidly changing priorities
- Strategic and analytic thinking
- Strong sense of responsibility
- Ability to plan and coordinate several submissions and projects at the same time
- Goal oriented with meeting internal and external deadlines e.g. regulatory authorities
- Team player who is self-motivated and used to work with high level of autonomy
- Solid command of spoken and written Regulatory English for working in international teams and within the company

Major Contacts

Internal

Medical affairs incl. drug safety, quality assurance, marketing, product launch coordination, demand management, global regulatory affairs

External

German Health Authorities, RA experts, consultants, lawyers, manufacturers, licensors, pharm. industry associations

Full training will be provided.

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.