Regulatory Affairs Officer - M/F/D

ProductLife Group's mission is to improve human health by delivering regulatory compliance services for the safe and effective use of medical solutions. Since almost 30 years, PLG supports clients through the entire product life cycle, combining local expertise with global reach spanning more than 130 countries. It provides consulting and outsourcing services in the areas of regulatory affairs, quality and compliance, vigilances and medical information, covering both established products and innovative therapeutics & diagnostics. With a goal of continuously improving the value delivered to people and customers, PLG is committed to long-term partnership, innovation, flexibility, and cost efficiency.

ProductLife Group has known an incredible growth during the last years and the Regulatory Affairs Officer will be part of the development of our local presence in Germany to sustain our development as our goal is to fulfill the targets displayed in our plan EnergiZe 2025.

The Regulatory Affairs Officer will take part in the local regulatory affairs activities performed in Germany for some of our biggest clients.

Missions/Responsibilities

• Contribute to the production of client administrative documents to be included in regulatory submissions

• Compile regulatory dossiers in accordance with national requirements.

• Document and track regulatory submissions and regulatory authority approval inside document management systems

• Provide regulatory support to clients and associate companies.

• Liaise with external regulatory authorities as required.

• Provide review of packaging texts.

• Provide format review of Summary of Product Characteristics, Patient Information Leaflets and labelling (e.g. QRD compliance check).

• Provide on-going regulatory support to the Regulatory Affairs Manager and to project teams to ensure regulatory concerns are planned and accounted for and the relevant data are generated to meet project objectives.

• Contribute to data entry in PLG tools enabling measurements of KPI, metrics for regulatory services supplied by the platform/hub

• Assist in the preparation of Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs)

Education

University background and/or experience in Regulatory affairs.

Bachelor's degree in a science related field, or scientific education, preferably as PTA, or A levels with data entry experience.

Experience

At least one year of Regulatory Affairs experience

Required Skills

• Native German mandatory along with fluent English

• Excellent organizational and interpersonal skills

• Ability to work well within a team

• Process oriented 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

Location: Haan, Germany

Salary: Based on profile

If you feel like you want to be part of a growing and dynamic team, send your application to flaporte@productlife-group.com !

Person in charge of this recruitment: Foulques Laporte, Talent Acquisition Officer

You can find our other openings at https://www.productlifegroup.com/careers/ !

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