ProductLife GROUP

ProductLife Group provides world-class regulatory outsourcing and consulting services for the global life sciences industry. Headquartered in Paris, ProductLife Group has offices in countries across Europe, the Middle East, Asia, Africa, Latin America, and North America.

ProductLife Group was founded in 1994 and has since become a global industry leader, thanks to the firm's driven and talented employees, who are always motivated by a supportive team environment as well as opportunities to learn and to grow professionally. Employees and company partners are located in offices worldwide to support clients and drive continued growth. If you're enthusiastic, if you welcome challenges, and if you want to grow professionally with a management team committed to your development, apply to join us.

Interested in this position? Either send your application to recruitment@productlife-group.com or contact your recruitment officer:

Henri Pena
hpena@productlife-group.com

Job title: Regulatory Affairs Manager

Locations : Belgium-Ninove

Contract : Permanent contract

JOB DESCRIPTION AND RESPONSIBILITIES

As a result of a new project we are now seeking a Regulatory Affairs Manager responsible for ensuring the delivery of regulatory activities performed on the RA Platform/the Hub.

MAIN RESPONSIBILITIES

- 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.
- Review tasks for, support and mentor Regulatory Affairs Officers and Associates.
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CANDIDATE PROFILE

ProductLife Group applies the principles of equality and diversity in the workplace and opposes all forms of unlawful discrimination.

EDUCATION & EXPERIENCE

- Life Sciences related fields (Bachelor's or higher graduate degree in a science related field)
- Minimum of 3 years experience, this experience should include a proven understanding of the regulatory process and experience in leading a project to successful completion.

SKILLS

- Experience in a regulatory affairs department
- Knowledge of medicinal products registration/life cycle maintenance in Europe (NP, MRP,DCP and CP)
- Knowledge of EU and Belgium registration
- Experience in Labelling in Belgium
- Process orientated with good attention to detail
- Effective oral and written English communication skills
- Fluent in English and Dutch for daily contact with internal and external partners.