



Pharmacovigilance Manager

Germany-Haan

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 an increase in workload we are now seeking a PV Manager responsible for contributing to pharmacovigilance activities performed on the PV Platform which includes pre and post marketing activities and interaction with health authorities on behalf of ProductLife customers. They will also assist the Drug Safety Co-ordinator with planning and distributing the daily workload.

Primary Responsibilities

- To contribute to the production of client administrative documents to be included in regulatory submissions.
- Undertakes data entry and document management for Pharmacovigilance (PV) aspects of allocated studies.
- Systems Management and Administration.
- Understand and interpret clinical and scientific reports to allow the accurate capture of safety data.
- Responsible for the triage, case processing and document management of safety documentation. Safety information to manage includes Adverse Events (AEs), Serious Adverse Event (SAE) reports from clinical trials, spontaneous reports, health authority reports and literature reports.
- Contributing in compilation of aggregate reports in PV
- To manage the safety mailbox and ensure that case timelines are accurately assessed and recorded for continued compliance.
- Liaise with health care professionals (HCP) & Study investigators to collect follow up information.
- Generate line listings for the production of aggregate reports.
- Assist the Drug Safety Specialists, Drug Safety Officers and other project staff with PVG project related tasks as required.
- Run literature searches on behalf of clients and perform a review of the abstracts to identify relevant safety information.

Other

- Assist in the preparation of Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs).
- Assist in the management of ProductLife's Quality Management System.
- To participate in training as required for ProductLife staff.

- To comply with the company's policies and procedures to meet statutory, quality and business requirements within the overall strategy and objectives.

Candidate profile

Education and Experience

- Job specific training will be provided in house
- Minimum of 3-4 years of working experience in PV
- In depth knowledge of GVP and local legislation, PV documents (RMP, PSUR AND PSMF)
- Knowledge of signal detection
- Experience in case handling activities and aggregate reporting
- Experience of working in a team
- Experience of leading a project

Key skills

- Excellent organisational skills
- Experience of client communication
- Project management
- Fluent in German and English for internal and external communication with partners

Core competences

- Good interpersonal skills and ability to make informed decisions
- Process oriented
- Good understanding of safety database software, MS Word and MS Excel

ProductLife Group supports the principle of Equality and Diversity in employment and opposes all forms of unlawful or unfair discrimination on the grounds of any form of protected categories.

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 send a Curriculum Vitae and covering letter by e-mail to recruitment@productlife-group.com