Vigiland Pharma

Business Without Side-effects

Based in Budapest, Hungary, Vigiland Pharma Ltd. has been providing pharmacovigilance and regulatory services for more than 8 years. Our unique quality assurance system ensures complete compliance.

Main services

Pharmacovigilance

- Collection, evaluation, assessment and reporting of safety information
- Global/local literature monitoring process including search strategy suggestions
- Maintenance of a pharmacovigilance system (PSMF) for pharmaceutical companies as required in the EU
- Nominating European Union Qualified person for pharmacovigilance
- Nominating a local contact person for pharmacovigilance as required by local legislation in Hungary
- 24/7 availability
- Risk management plan development and maintenance including educational material management in Hungary
- Support sales and marketing with regulatory and pharmacovigilance knowledge to ensure compliance with relevant regulations
- Loading and managing product data into the xEVMPD
- Reporting serious/non-serious case safety reports (ICSR) to EudraVigilance
- Performing risk-based assessment of pharmacovigilance system
- Performing audits of the pharmacovigilance system
- Tailor-made pharmacovigilance trainings on demand

Clinical Studies

- Study related activities in various fields within clinical research.
- Covering projects from the pre-study–start-up phase to closure-post-study activities
- Ensuring and auditing compliance of the specified study activates and auxilaries such as regulatory reporting not limited to the territory of Hungary.
- Perform monitoring the compliance of the sites, external partners both in-house and onsite horizontal or longitudinal

- Providing an individual or whole team for the required position with 8+ years' experience in clinical research.
- Lifecycle management of studies (people and functional management)
- Establishing-writing / reviewing study protocol for local studies including relevant documentation, such as case report form, adverse event reporting form
- Monitoring with 8+ years' experience in clinical research, with a university degree either in medicine or pharmacy. Their experience covers almost all therapeutic areas, such as numerous fields of internal medicine, CNS studies, oncology and also less "popular" fields, like dermatology, gynaecology or ophthalmology.
- Safety support with supporting adverse events reporting, provide medical assistance for handling serious adverse events, providing safety training for sites, ensure the preparation and reporting of the Adverse Event Report on site, ensure Adverse Events recording, 24/7 surveillance
- Providing auxiliary activities such as organizing investigators' and personal team meetings included full-services

Medical device

"For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union."

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