

Head of Drug Safety & Pharmacovigilance (m/f)

Thrombogenics NV has successfully entered Phase III for its most advanced development candidate and offers now a new position for a Head of Drug Safety and Pharmacovigilance. ThromboGenics is developing Microplasmin as a non-surgical treatment for focal vitreomacular adhesion (or traction), a condition in which the vitreous gel has an abnormally strong adhesion to the retina.

It is the intention of Thrombogenics to become a fully integrated company focusing on the commercialisation of Microplasmin in eye diseases as well as the development of innovative medicines for the treatment of vascular diseases and cancer. To enable the commercialisation strategy of Microplasmin and to further support the development of its clinical projects the company is actively searching for a Head of Drug Safety and Pharmacovigilance.

The candidate (m/f) will report to the Clinical Director Europe.

Challenges:

- Function as clinical drug safety expert with global responsibility, specifically she/he will be the main contact person for all safety matters regarding Thrombogenics' lead compound Microplasmin. Part of this function involves writing the risk management plan as part of the eCTD and the management of relevant annual safety reports.
- Responsible for setting up a global and operational postmarketing pharmaco-vigilance system for Thrombogenics' lead compound Microplasmin. The system set-up will involve the management/selection of third party providers delivering services in pharmacovigilance as well as the management of the internal resources. The system will be compliant with current ICH and the relevant local authorities' guidelines; therefore he/she will be the lead in developing the standards and processes in order to maintain the system. The person will act as the QP PV of the company.
- Responsible for the maintenance of the current clinical pharmacovigilance system which involves all Thrombogenics' products currently in clinical development. The person will oversee the writing and reviewing of case narratives, IND/CTA annual report safety sections, periodic reports and is proficient at generating and/or reviewing drug safety related content for clinical study reports, manuscripts, protocols, analysis plans and other written documents in support of clinical development and medical affairs initiatives.
- He/ she will work together with the Head of Quality in case of drug safety regulatory inspections and audits.

Qualifications:

- MD with the qualifications to act as a qualified person for Pharmacovigilance in accordance with EU legislation.
- Strong knowledge of global clinical safety/pharmacovigilance regulations and ICH guidelines.
- Minimum of 6+ years pharmaceutical industry experience with a minimum of 4 years of global safety, pharmacovigilance and risk management experience; this from the perspective of global product development as well as the commercialization.
- Excellent interpersonal, team management and leadership skills are required.
- Analytical expertise in understanding complex issues and their consequences.
- Stress resistant and excellent in crisis management.
- Fluent in English, both oral and written

We offer:

- A highly capable, creative and motivated operational team where innovation and flexibility are key characteristics
- Competitive salary

Contact:

Please submit your resume at hr@thrombogenics.com or contact Laurence Raemdonck, HR Manager for a confidential discussion and to find out more about this role.

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