REGULATORY AFFAIRS & PV OFFICER BeNeLux

Tina Phan
Executive Search Consultant
0032.486.60.36.66
tina.phan@hronegroup.com

Mathieu Staes
Business Development Manager
0032.478.62.63.15
mathieu.staes@hronegroup.com

HR One Group
Henkelsite
Persilstraat 51 bus 01
3020 Herent - Belgium

tel. +32 16 29 78 31
fax +32 16 62 30 13

www.hronegroup.com

Erkenningsnummer
VG. 1690/BO B-AB10.018.

Our client is looking for a dedicated **Regulatory Affairs & Pharmacovigilance (PV) Officer** to join their team in the BeNeLux region. The ideal candidate will have a strong background in regulatory compliance, safety reporting, and a keen eye for detail to ensure that all pharmaceutical products meet the necessary legal requirements. You will be responsible for maintaining up-to-date knowledge of regional regulations, preparing and submitting documentation to regulatory agencies, and monitoring the safety of our products post-market. Strong communication and organizational skills are essential for this role.

THE POSITION

Regulatory Affairs:

- Marketing Authorisation application, variation, renewal:
  - Review of documentation provided by Global Regulatory Affairs.
  - Preparation of local documents required for the submission of MAs, variation, renewal…
  - Communication with health authorities in Belgium, The Netherlands and Luxembourg regarding local submissions
  - Review and approval of translations and artworks
- Provide regulatory input and active support in:
  - new product launches
  - Initiation and follow up of Patient Support Programs in collaboration with the local medical team
  - design, dossier preparation and submission of Early Access Programs (CUP, MNP,…) in collaboration with the local medical team
  - Preparing and submission of local Risk Minimization Plans
- Ensure deviations and non-conformities are registered in timely matter
- Support creation and revision of SOPs and training of these
- Support sales force with regards to request for samples
- Providing support and guidance on regulatory strategies.
- Keep the local teams informed of upcoming and ongoing variations and timelines
- Preparation of meetings and assisting during the meetings when necessary (internal and external)

Pharmacovigilance:

- Be the local contact person for Global Pharmacovigilance (GPV) in the BeNeLux region
- Act as interface between EU-QPPV, GPV, the external PV vendor and local regulatory authorities as required
- Secure the integrity and high standards in the handling of adverse events and risk management activities at local level, including for:
  - follow-up locally on adverse events/safety reports
  - responses to regulatory questions on patient safety matters in national language,
  - implementation of local risk minimization activities

HR One Group
Henkelsite
Persilstraat 51 bus 01
3020 Herent - Belgium

tel. +32 16 29 78 31
fax +32 16 62 30 13

www.hronegroup.com

Erkenningsnummer
VG. 1690/BO B-AB10.018.

- Ensure monitoring of local guidance and pharmacovigilance legislation, including forwarding information to GPV, take the necessary actions at local level and implement the change within the set timelines to ensure local requirements are being met.
- Ensure PV related agreements (e.g. contracts with ESP, PSP providers, Market Research providers) include PV clauses.
- Ensure that all local potential sources of safety information, including affiliate email inbox, websites, digital and social media forums, and customer relationship management system, are monitored every local business day
- Ensure that local literature review is performed as per global and local requirements
- Responsible for the transfer of safety data from source documents to other medium.
- Ensure reconciliation of safety data between the affiliate and other internal and external sources
- Responsible for oversight of any vendor performing PV activities locally
- Support creation and revision of local SOPs and training of these
- Provide support during audits/inspections at local level
- Assist the timely closing of findings related to PV inspection/PV audits at local level
- Ensure deviations and non-conformities are registered in timely matter
- Organise onboarding training for new Benelux employees
- Organise onboarding training for new local PV vendors and ensure annual refresher training is performed for all local PV vendors

REQUIREMENTS

Education/Learning Experience/Work Experience

- Minimum a bachelor's degree in a life science discipline (such as pharmacy, chemistry, biochemistry, biotechnology, chemical or biomedical sciences).
- Minimum 2-3 years' experience in regulatory affairs and/or PV environment.
- Knowledge of and experience with relevant EU and local (BE/NL) regulations.

Skills/Knowledge/Languages

- Fluent communication skills in Dutch, French and English (written and oral).
- Strong analytical skills, accurate and detailed while keeping the goal in mind.

Personal Attributes

- Ability to handle and enjoy complex and changing environments.
- Positive, optimistic and can-do mindset.
- Proactive and hands-on mentality.
- Show ownership.
- Solution oriented.
- Ability to handle multiple projects simultaneously.
- Able to shift gears and to deliver, also within sometimes tight timelines.
- Eagerness to learn & grow and stay up to date.

THE OPPORTUNITY

As a Regulatory Affairs & Pharmacovigilance (PV) Officer in the BeNeLux region, you will play a pivotal role in ensuring the safety and regulatory compliance of our pharmaceutical products. This position offers the opportunity to work at the intersection of science, law, and healthcare, allowing you to contribute directly to the well-being of patients and the success of our

company. You will collaborate with a dynamic team of professionals, gain in-depth knowledge of regional and international regulations, and be at the forefront of the latest developments in the pharmaceutical industry. Additionally, this role provides a platform for professional growth, with opportunities for career advancement and continuous learning in a supportive and innovative environment.

HR One Group
Henkelsite
Persilstraat 51 bus 01
3020 Herent - Belgium

tel. +32 16 29 78 31
fax +32 16 62 30 13

www.hronegroup.com

Erkenningsnummer
VG. 1690/BO B-AB10.018.