

ARSANNE Consulting is looking for a Benelux RA, QA and Vigilance Manager for the BENELUX affiliate of an entrepreneurial international pharmaceutical group. Knowledge of BENELUX pharmaceutical regulatory environment is an important asset.

Your Mission :

You report directly to the General Management and you are responsible for Benelux. You'll be in charge of the introduction and management of new and existing brands manufactured by the group within the BENELUX market.

Your Duties and Responsibilities :

- Responsible Pharmacist assume the function in relation to GDP (article 12ter of the medicines law of 25 March 1964) as described into Royal Decree of 14 December 2006.
- Acts as the local person for medical device distributor in accordance with the legislation of March 18th, 1999.
- Notified as the contact person for quality defects/falsified medicines at AFMPS/FAGG.
- Assumes the role as local contact person for pharmacovigilance as described into RD 14 December 2006.
- Assumes the role as RIP in relation to publicity and medical information as described into RD 7 April 1995.
- Local Regulatory Contact Person for Marketing Authorizations.
- Evaluates and approve external consultants.
- Evaluates market access dossier preparation, attend pre-meetings at FOD Economy and/or INAMI/RIZIV where appropriate.
- Evaluates & Approval of reworks on medicines.
- Provides quality & safety training to medical representatives Benelux personnel.
- Manages R&D budget.
- Reviews and approves PUB material for use.
- Maintains the box platform.

Contacts :

Internal: International, affiliates & Benelux Corporate, local medical representatives, physicians.

External: Local Inspections, Local Health Authorities, SPF/FOD, consultants, local distributor, and all related stakeholders & partners

Required knowledge & Skills

Minimum requirements:

- Pharmaceutical degree
- Knowledge of GDP on medicines and/or medical devices
- Knowledge of medical information and publicity guidelines

Desirable requirements

- Knowledge of French, Dutch and English language
- MS Office