

VACATURE

MANAGER REGULATORY AFFAIRS

JOB DESCRIPTION

POSITION PURPOSE

The Manager RA manages the regulatory affairs and external affairs at Heel Belgium. This person acts as link between the involved and beneficial parties concerning regulatory affairs within Heel Belgium.

This role includes the representation of Heel Belgium within relevant trade associations and towards governmental bodies.

The Manager RA manages:

- 1 RA Officer
- 1 RA coordinator
- 1 RA support

He/She ensures alignment with all other departments within Heel Belgium and with the relevant departments of other subsidiaries and with those of Head Quarters.

Roles and responsibilities

1. Supervise and manage the Regulatory Affairs actions for Heel Belgium

1.1: Manage the existing product licences and the obtainment of new registrations of homeopathic (and if needed phyto products, food supplements, medical devices or cosmetics) medicinal products.

- Coordinate the complete process for regulatory submissions in line with the strategy and by this ensures timely registration of all homeopathic medicines (before 31/12/2025)
- Ensures that all regulatory obligations of the manufacturing authorization holder are fulfilled. Update licensing and collect information on registration instructions and regulations for Heel and specific contract manufacturing customers.
- Establish constructive relations with authorities, governmental bodies and KOL's
- Manage the final product submissions. Negotiate with regulatory authorities to obtain timely product approvals in line with internal Heel guidelines.

- Proactive follow up and monitoring of the current legal and regulatory requirements concerning registration of products (medicines, cosmetics, med dev., ...)
- Handle the planning and execution of renewals and variations
- Manage the obtainment of the Free Sales Certificates for foreign countries
- Responsible for the 'Declaration of Conformity' for registrations of variations on a MA.

1.2: Ensure that all promotional materials used by Heel Belgium are marketing proof but in line with the existing legislation and guidelines on information and publicity (RIP)

- Together with the Head of S&M, establishes an appropriate and constructive internal procedure for approving advertising and various promotional materials and events
- Participate and act as final RA check for the approvals of all publications and promotions being compliant with the existing regulatory guidelines.
- Verification and approval of the compliance of the SPC, the leaflets, promotional materials, packaging materials and their translations (sign "Declaration of Conformity") (OZB 469).
- Ensure guidelines with regards to dealing with HCP, samples are updated, installed and trained within the organisation for the applicable roles
- Pricing dossiers for FOD – develop and maintain an internal and external agreed vision that ensures a specific homeopathic medicines price structure will be installed.

1.3: Manage the alignment and collaboration with other departments

- Ensure internal training, updates and feedback are provided on new legislation, registration processes, pricing, authorisations, product development, etc.
- Ensure alignment with Production, QA and QC
- Ensure alignment with S&M
- Manage the annual expenses of RA (e.g. registration fees) and ensure communication on invoicing of RA fees to HQ.

1.4: Develop and maintain knowledge and profound insights with regard to national and European legislation in the field of homeopathic medicines among other medicinal products.

2. Represent Heel Belgium in trade associations, working groups and towards governmental bodies in support of the GM.

4.1: Act as first and single point of contact (24/24) for the authorities with regards to RA matters linked with the communications and promotions of our products.

4.2: Active member Transparency commission (installed since July 2008 via RD 23/06/2008),

- Include feedback from authorities and other stakeholders in the RA management
- Provide input with regards to expenses and budgets within this part of the FAMHP

4.2: Represent the company and play an active steering role within in the Homeopathy Belgium Industry Association (previous RASH: Regulatory Affairs Society of Homeopathic Products)

- Ensure clear alignment exist between the aim for Heel Belgium and for the associations.
- Ensure transparent communication is installed within the members of the association
- Ensure transparent communications towards internal departments within Heel Belgium

4.3: Participate actively in international standardisation and working groups

- Ensure Heel Belgium provides direction and benefits to such groups
- Align with HQ department
- Align and report internal at Heel Belgium
- Ensure up to date RA information and foresee transfer of information between Heel Belgium and Heel HQ

QUALIFICATIONS / KNOWLEDGE / EXPERIENCE

1. Education:

Master in a science related field
Understanding of business management and governmental affairs is desired.

2. Professional knowledge and/or experience:

- Minimum 3 years in the management of RA and regulatory compliance.
- 5 year of regulatory affairs experience in the pharmaceutical industry, actively supervising and writing clinical regulatory documents. (homeopathic medicinal products, phyto products, food supplements, medical devices or cosmetics).
- Experience in the direct interactions with several associations presenting industry, HCP's, patients, governmental bodies, etc.
- Understanding of documentary techniques: collection development, document description (including indexing), use of information sources, library automation and database management.
- Hands on effectiveness for internet searches and retrieval of scientific, regulatory sourced information.
- Strong working knowledge of Windows environment and RA related documents.
- Eagerness to expand insights and get involved in legal and regulatory matters linked with the manufacturing and distribution of medicinal products (e.g. pharmacovigilance, environment, safety, ...)

3. Languages:

- Excellent communication skills in Dutch, French and English.

COMPETENCIES / BEHAVIOURS

- Good communicator
- Sense for relevant synthesis while keeping in mind the big picture
- Effective self and time management in order to deliver within strict timelines
- Open attitude towards other insights and perspectives
- Proactive approach to issue handling and problem solving ability
- Prepared and flexible towards changes in policies and procedures
- Critical constructive mind-set.
- Ability to manage, interact with all level of people in a positive manor
- Team player and seeing the mutual benefits within the company
- Ability to maintain confidentiality
- Identifies with Heel's Vision & Mission