VACATURE

HEAD OF REGULATORY AFFAIRS – QUALITY CONTROL / Q.P.

JOB DESCRIPTION

POSITION PURPOSE

The QP - Head of RA-QC manages the regulatory affairs, external affairs, pharmacovigilance and the quality control at Heel Belgium.
This person acts as QP (Qualified Person) and as RIP (Responsible for Information and Publicity).
This role includes the representation of Heel Belgium within relevant trade associations and towards governmental bodies.
He/She ensures relevant actions with regards to pharmacovigilance.

The QP- Head of RA-QC manages:

- 1 QC Manager and indirect 2 Labo specialists
- 1 RA Officer
- 1 RA coordinator
- 1 RA support library / documentalist

The QP- Head of RA-QC is a member of the management of Heel Belgium.
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. Act as Qualified Person for Heel Belgium

1.1: Manage the role of QP and perform batch certification and batch release

- Manage the compliant QC process in the company and ensure regular trainings and measurements in order to enable compliant product releases
- Act as first and single point of contact (24/24) for the authorities with regards to QC and product releases
- Manages these matters during inspections or audits in close collaboration with the other relevant departments

1.2.:Manage Pharmacovigilance

- Ensures the compliant pharmacovigilance process in the company and plans regular trainings and measurements

- Report to the competent authorities serious adverse effects (ICSRs), periodic safety reports (PSURs) and reports on studies of post-authorization safety
- Act as first and single point of contact (24/24) for the authorities with regards to PV and represent the PV matters as responsible PV during inspections and audits

1.3: Execute role of RIP (Responsible Person for information and Publicity)

- Participate and act as final RA check for the approvals of all publications and promotions being compliant with the existing regulatory guidelines.
- 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.
- Install a constructive communication with the internal departments in order to ensure the promotional communications are in line with the existing RA guidelines

2. Manage the QC operations for Heel Belgium

2.1: Ensure all manufactured or imported products that are marketed in Belgium are compliant to the existing legislation and guidelines (GMP, GDP, QC, …)

- Ensures the knowledge and expertise within QC and the labo are kept up to date
- Applies relevant international standards into company product related requirements
- Ensure an effective pharmaceutical quality control management system
- Provide regulatory input related to manufacturing authorization updates

2.2: Accountable for the performances and executions of QC and the labo

- Link the relevant standards with Heel requirements and vice versa
- Monitor the operations and overall performances of QC and labo

2.3.:Manage the alignment and collaboration with other departments

- Ensure clear updates are provided on existing legislation, processes, etc.
- Ensures internal understanding and alignment on the on-going QC matters
- Ensures the collaboration with the department of Production in order to achieve and maintain the relevant standards.
- Manage the annual expenses of your department

3. Manage the Regulatory Affairs for Heel Belgium

3.1: 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., …)
- Manage the obtainment of the Free Sales Certificates for foreign countries
- Responsible for the 'Declaration of Conformity' for registrations of variations on a MA.

3.2: 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
- 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.

3.3: 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.
- Manage the annual expenses of your department (e.g. registration fees)

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

4. Able to act as principle spokesperson for Heel Belgium - Represent Heel Belgium in trade associations, working groups and towards governmental bodies.

4.1: Active member Transparency commission (installed since July 2008 via RD 23/06/2008),
- Include feedback from authorities and key opinion leaders 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

4.3: Participate actively in international standardisation and working groups
- Ensure Heel Belgium provides direction and benefits from such groups
- Align and report internal at Heel Belgium and with HQ on all topics

QUALIFICATIONS / KNOWLEDGE / EXPERIENCE

1. Education:

   Master in pharmacy, **with a degree of Industrial Pharmacist.**
   Understanding of business management and governmental affairs is desired.

2. Professional knowledge and/or experience:

   - Minimum 3 years in the management of pharmaceutical manufacturing and quality control as QP and regulatory compliance.
   - 10 years of regulatory affairs experience in the pharmaceutical industry, actively supervising and writing clinical regulatory documents.
   - Minimum 3 years of 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, manufacturing and quality sourced information.
- Strong working knowledge of Windows environment and RA and QC related documents.

3. Languages:

- Excellent communication skills in Dutch, French and English.

COMPETENCIES / BEHAVIOURS

- Analytical skills with sense for relevant synthesis while keeping in mind the big picture
- Effective self and time management in order to deliver within strict timelines
- Proactive approach to issue handling and problem solving ability
- Prepared and flexible towards changes in policies and procedures
- Critical constructive mind-set.
- Good communicator
- 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