

VACATURE

QUALIFIED PERSON

JOB DESCRIPTION

POSITION PURPOSE

The QP manages the specific tasks and roles within Heel Belgium with regards to Products release and the quality control at Heel Belgium.

This person acts as QP (Qualified Person) and reports to the GM, while functional reporting will occur within Production and Quality.

This role includes the representation of Heel Belgium towards governmental bodies.

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, when required.

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.: Learning and Development

- Ensures insights and knowledge concerning pharmacovigilance process in the company
- Ensures insights and knowledge concerning Information and Publicity
- Ensures insights and knowledge concerning all other related actions and processes related to QA, QC and RA in alignment with these departments

2. Support all activities within QA and QC operations within Heel

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: Ensure insights in the performances and executions of QA, QC and the labo
- Link the relevant standards with Heel requirements and vice versa
 - Follow the operations and overall performances of QA, QC and labo
- 2.3.:Manage the alignment and collaboration with other departments, subsidiaries or business partners of Heel Belgium
- 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.
- 2.4: Supports RA in the internal alignment with QA and QC.
- Link the relevant standards with Heel requirements and vice versa
 - Follow the operations and alignment QA, QC and RA
- 3. Able to act as principle spokesperson for Heel Belgium - Represent Heel Belgium in trade associations, working groups and towards governmental bodies.**
- 3.1: Represent the company when required in relation to all QP related actions.
- Ensure alignment exist between the aim for Heel Belgium and for the governmental bodies.
 - Ensure internal and external transparent communication is installed
- 3.2: 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.
 Licensed QP
 Understanding of business management and governmental affairs is desired.

2. Professional knowledge and/or experience:

- Minimum experience in the management of pharmaceutical manufacturing and quality control as QP.
- 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 QA 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