JOB DESCRIPTION
RA Employee

"This job description is intended to convey information essential to understanding the scope of the job and the general nature and level of work performed by job holders within this job. But, this job description is not intended to be an exhaustive list of qualifications, skills, efforts, duties, responsibilities or working conditions associated with the position."

POSITION PURPOSE

The Regulatory Affairs Employee provides clerical support to the Regulatory Affairs team, maintains and organizes the team's trackers and databases, performs data entry and maintains regulatory document files of the medicinal products for human and veterinary use and of the non-medicinal products (cosmetics, food supplements, medical devices, animal feed, …).

The different roles of the function require a hands on mentality and good planning and organization skills. The person guarantees punctual administrative follow-up and status overviews of all dossiers or projects. The person supports the team by ensuring that products are manufactured, marketed and distributed in compliance with appropriate legislation.

ESSENTIAL DUTIES AND RESPONSABILITIES

1. *Portfolio*

- Clerical support the regulatory activities for the licensing of food supplements (including new ingredients), cosmetics, medical devices, animal feed and homeopathic medicines for Heel and specific contract manufacturing customers:
  - Prepare, write and edit the product and packaging information.
  - Assist in collecting, writing and reviewing of key regulatory documents (e.g. application form, declarations, certification,…)
  - Edit the lay-out of labels in Illustrator CS6 and coordinate the changes to secondary packaging material with the printing agency (e.g. proofreading of mock-ups).

    - Prepare and submit notification/registration/authorisation dossiers on the concerned platforms (e.g. CESP, foodsup,…).
- Pricing medicine portfolio:
    - Prepare and collect the elements needed for a price dossiers.
    - Draft the dossier in the adequate format.
    - Submit the dossier to the NCA.
    - Act as a contact person for internal and external stakeholders.
    - Ensure the administrative overview and filing.

2. *Customers*

- Assist in collecting information from various departments and/or headquarters to support regulatory or interdepartmental projects.
- Support in the reporting on the status of the products or projects and in the responding to questions of internal (management, other departments) and external customers (headquarters, regulatory authorities) on the Heel or Contract Manufacturing portfolio.
- Inform proactively and timely internal and external customers on the status of regulatory dossiers.
- Maintain team trackers and databases (server, portfolio,…) in line with most recent regulatory status of products.
- Support our customers with the submission of technical dossiers when needed and with certificates upon request (allergene declarations, certificate of conformity, …)

3. *Learning: keep informed on the current scientific and legal standards*

- Collecting and collating of information in a variety of formats.
    - Scientific documents (Ph. Eur., HAB, Radar Opus,…)
    - Legal documents (FAGG, FOD Volksgezondheid, CBG, EMA, EFSA, HMPWG, …)
- Continuously improve knowledge regarding regulatory submissions and requirements.

4. *Provide support to the Regulatory Affairs Manager*

- Reporting of activities, including providing input for monthly internal reporting
- Budget process: provides the requested input on planning of expenses and dossiers
- Participate in the approval process of medical marketing materials for non-medicinal products and of medicinal products, by checking if all publications and promotional materials are compliant with the SmPC, the leaflets and the authorized claims.
- Follow-up and organisation of the RA mailbox
- Internal and external questions (e. g. update notifications, …)
- Preparation of meetings and assisting during the meetings (e.g. taking minutes) when necessary

QUALIFICATIONS / KNOWLEDGE / EXPERIENCE

Basic Education and technical capacities

- Minimum a bachelor's degree in a life science discipline or office management
- Appropriate computer skills (Word, Excel, Powerpoint, Outlook, Adobe Acrobat, Knowledge of Illustrator CS6 is a plus)

Professional experience

- First experience in a regulatory affairs environment or in an administrative supporting role.
- Passionate about food supplements, (homeopathic) medicines, cosmetics, medical devices, animal feed,… and eager to learn the relevant legislation

Language Skills

- Fluent communication skills in Dutch, French and English (written and oral).

COMPETENCIES / BEHAVIOURS

- Ability to handle and enjoying complex and changing environments
- Positive, optimistic and can do mind-set
- Proactive and hands-on mentality
- Shows ownership
- Solution oriented
- Excellent communication skills
- Strong analytical skills, accurate and detailed while keeping the goal in mind
- Good planning and organization skills
- 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
- Identifies with Heel's Vision & Mission