JOB DESCRIPTION
Regulatory Affairs Officer

POSITION PURPOSE

The Regulatory Affairs Officer ensures the appropriate licensing, marketing and legal compliance of medicinal products for human and veterinary use and of non-medicinal products (cosmetics, food supplements, medical devices, animal feed, …) The role functions with a hands on mentality and an entrepreneurial mindset for new to develop products and for the existing portfolio. He / She acts as a link between company and regulatory authority, ensuring that products are manufactured, marketed and distributed in compliance with appropriate legislation. He / She guarantees shared understanding and alignment on all dossiers or projects.

ESSENTIAL DUTIES AND RESPONSABILITIES

1. *Portfolio:*

- Manage 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.
- Involves pro-actively within the development of new products.
- Prepare and submit notification/registration/authorisation dossiers:
    - Technical and scientific writing.
    - Preparing, writing and coordinating the product and packaging information.
    - Lay-out changes of labels in Illustrator CS6 and coordination of changes to secondary packaging material with print agency.
    - Coordination and follow-up of local regulatory submissions.
    - Contact and exchange with regulatory authorities and notified bodies.
    - Facilitate shared understanding within Heel
- Ensure that the portfolio or new to develop products are manufactured and distributed in compliance with the approved authorisation, regulatory guidelines and legislation.
    - Initiate action when needed by preparing (technical and scientifical writing) and coordinating the appropriate regulatory dossiers to inform the authorities on changes or other requirements.
    - Update licensing and collect information on registration instructions and regulations for Heel and specific contract manufacturing customers.

2. *Customers:*

- Provide regulatory input and active support in new product innovations and work closely together with product innovation manager on development of new formulas and to find the most suitable health claims for new products.
- Reports regularly on the status of the products or projects and provide response 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 or on any regulatory/scientific change which might have impact on the compliance of the portfolio to the applicable legislation.
- Updating system (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 (allergen declarations, certificate of conformity, …)

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

- Collecting, collating and evaluating information in a variety of formats.
  - Scientific documents (Ph. Eur., HAB, Radar Opus,…)
  - Legal documents (FAGG, FOD Volksgezondheid, CBG, EMA, EFSA, HMPWG, …)
- Proactive follow up and monitoring of the current legal and regulatory requirements concerning registration of products (medicines, food supplements, cosmetics, medical devices, animal feed, …) and initiate implementation of relevant changes.
- Share proactively information on new regulations, guidelines or other relevant matters concerning our products and projects.

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.
- Internal and external questions (e. g. update notifications, …)
- Providing support and guidance on regulatory strategies.
- Preparation of meetings and assisting during the meetings when necessary (internal and external)

QUALIFICATIONS / KNOWLEDGE / EXPERIENCE

Basic Education and technical capacities

- Minimum a bachelor's degree in a life science discipline (such as pharmacy, chemistry, biochemistry, biotechnology, chemical or biomedical sciences)
- Appropriate computer skills (Word, Excel, PowerPoint, Outlook, Adobe Acrobat, Knowledge of Illustrator CS6 is a plus)

Professional experience

- Experience (3-5 years) in a regulatory affairs environment.
- Knowledge of and experience with EU and local (BE/NL) regulation of food supplements, (homeopathic) medicines, cosmetics, medical devices, animal feed,…
- Interest and experience in product development within existing or new to develop portfolio's.

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
- Open, curious towards potential new developments or out of the box ideas
- Strong analytical skills, accurate and detailed while keeping the goal in mind
- 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