# Regulatory Affairs Officer at Abbvie

## FUNCTION

*The Regulatory Affairs Officer will*:

Provide regulatory advices and support to the organization on the content of existing marketing authorizations and for products in development phase.
Support pharmacovigilance department on safety relevant matters in line with national requirements

**Main Accountabilities**
Follow-up with the Area team to obtain marketing authorizations for new pharmaceutical products, and work proactively with the affiliate commercial teams on local launch activities
Maintain marketing authorizations as required
Acts as Variations Officer and Carton & Label Operator (see separate function descriptions)
Liaise with Western European Regulatory Affairs and Corporate groups on regulatory matters
Liaise with national regulatory authorities as required
Comply with the Company's policies and procedures to assure consistency of the current local prescribing information with the CCDS in order to
- Ensure alignment within the organization
- Meet the expectations of regulatory agencies
- Implement approved label through defined artwork process
Liaise and attend meetings with other company functions to provide regulatory advice for new and existing products, including participation within affiliate Brand Team
May be involved in arrangement of national Scientific Advice with national Competent Authorities
Maintain awareness of current and new legislation/guidance (EU, BE, LUX) and ensure that work is in compliance with the statutory requirements
Write and update local procedures in compliance with the local regulation and internal policies and procedures, if applicable
Functions as a subject matter expert both within regulatory advertising and promotion and related functional areas
Verification of promotional materials for compliance with current approved labeling and pricing information.
If required, coordinating the review of parallel import samples

## QUALIFICATIONS

**Required Education / Knowledge / Experience**
Scientific/Biomedical degree/(Industrial) Pharmacist
Several years of Regulatory experience or in a related area in Healthcare industry
Good communication skills, both verbal and written
The ability to thrive in a changing environment and to re-prioritize workload to meet business needs
Good project management skills essential
Good Dutch, French and English language skills
Customer oriented
Strong analytical skills, accurate end efficient

## OTHER

- Reizen: Yes, 5 % of the Time
- Soort vacature: Experienced
- Planning: Full-time
- Job Level Code: IC

APPLY HERE