Traineeship Regulatory Affairs - BU Healthcare

RESPONSIBILITIES

- •Support in the lifecycle management of medicines (variations, renewal, etc.), medical devices and food supplement under OTC portfolio and preparation of documents to be submitted to Authorities
- •Support the team to prepare and submit the relevant documentation related to HCP materials and consumers advertising for the whole health brands
- •Support the process of medical information and advertising ensuring that promotional and educational materials are consistent with scientific ratio and meet applicable regulatory requirements
- •Ensure compliance with applicable local and global laws, regulations, guidelines and Company policies
- •Maintaining of local regulatory database and systems, archiving of regulatory documents and management of electronic directories
- •Monitoring of AIFA/Regulatory websites in order to detect law changes
- Checking product literature
- •Provide regulatory support and cooperate with marketing to ensure alignment on activities and on time delivery
- •Support in managing request from other departments and global regulatory
- •Support in the preparation of presentations for internal/external projects
- •Support the management of parallel import requests

REQUIREMENTS

- •Master degree in Pharmacy/Pharmaceutical Chemistry/Biotechnology
- Good level of English
- •Good knowledge of Microsoft Office/Power Point