Senior RA-GDD Labeling Associate

Job ID
REQ-10019382
Ago 19, 2024
Emirati Arabi Uniti

Sommario

The RA-GDD Senior Labeling associate Gulf & Levant is responsible to create and update the regional product information (RO2)/PIL as well as the artworks related to the new product registrations and the maintenance of the registered products. The scope of the responsibility will cover Gulf & Levant. RA-GDD Senior Labelling associate will be also responsible to create the NSS document for the whole portfolio to support the preparation of promotional materials for Gulf & Levant.

About the Role

Major accountabilities:

Labelling Project - PIL / packs Artwork update for Gulf / Levant

- Ensure early engagement with global teams, countries and labeling team to align on the submission strategy for NDAs, new indication, line extension and any other LCM activity affecting labeling.
- Prepare and coordinate the region- specific packs update for Gulf & Levant in line with the approved and updated US/ EU/ Swiss Product Information following a maintenance update or to reply to Health Authority specific request.
- Maintain an update Product Information leaflets in region-specific packs in line with the most updated and approved US/ EU/ Swiss PIL due to SLC, addition of a new indication, or any maintenance update that may impact the PIL text.
- Initiate and coordinate the translations and column designs with third party suppliers for leaflet artwork preparation.
- Coordinate with Medical Department for verification of translated product information leaflets.
- Prepare the relevant comparison table for PIL update for Gulf / Levant, where relevant.
- Communicate and coordinate with local RAs in Gulf / Levant the submission and approval of the updated PIL/ packs artworks.
- Launch and maintain region-specific packaging components (PIL and packs) via the One Art.
- Review and approve Printed Packaging Material Sheet (PPMS) received via One Art.
- Ensure timely submission and implementation of labeling changes through early and regular alignment with the cross-functional teams (NTO, global labeling, countries, supply chain, quality...)
- Collaborate with the quality team on any quality investigations related to labeling.
- Develop and maintain good relationship with the RA team in the Gulf/ Levant Clusters as well as Global RA/Labelling team.
- Create and maintain an updated NSS database for the whole active portfolio in Gulf/Levant in the Redi-Go (together with Labeling package).

Key performance indicators:

- Timely and accurate implementation of region-specific packs/PIL impacting product deliveries to the market
- Achievement of the compliance deliverables as per the Global targets when it is related to SLC/PIL/Pack update
- Maintain a 100% updated NSS database

Minimum Requirements:

Education :

- Pharmacist or Bachelor is Sciences (Chemistry, biology or any other scientific degree)

Experience & Skills:

- At least 2-3 years practical experience in Middle East Labeling/ Regulatory Affairs
- General Knowledge of global regulatory affairs.
- Ability to critically evaluate data from a broad range of scientific disciplines
- Knowledge/experience of regulations, guidelines for product Labeling/ life cycle maintenance
- Ability to work successfully with extended, multi- national project teams and coordinate activities simultaneously on multiple projects under pressure of time and workload
- Effective planning, organizational and cross-functional collaboration skills.
- Excellent English & Arabic required (oral and written)
- Excellent written / spoken interpersonal communication and negotiation skills
- Computer literacy

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Functional Area
Research & Development
Job Type
Full time

Employment Type
Regular
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