JOB PROFILE

Regulatory Affairs Manager (Cork, Ireland)

The role is mainly focused on the regulatory management of Recordati Corporate products all over the world, in strict cooperation with the International Pharma Sales Team at Recordati Ireland and with the International Regulatory Affairs team at the HQ in Milan, Italy. Recordati Ireland is responsible for over 1000 marketing authorizations in over 100 Countries.

The role is based in Cork and reports directly to the VP, International Pharma Sales and functionally to the Group Regulatory Affairs based in Milan, Italy.

Regulatory Affairs

Corporate and International Sales

- Ensures that International Sales team can optimize the footprint of Recordati products by ensuring timely coordination of regulatory activities between Recordati HQs, Recordati Affiliates when relevant, Regulatory Authorities and/or relevant third parties in the countries; In coordination with export managers and HQ Regulatory, defines international regulatory strategy considering the effective situation of our dossiers and the commercial plans of the International Sales division.
- In cooperation with the HQ regulatory team, and according to the HQ plans, is involved in the worldwide regulatory management of the marketing authorizations where Recordati Ireland is the MAH. This includes:
    - Management and appropriate archiving of official approval documents and correspondence from the Regulatory Authorities for all Recordati products where Recordati Ireland is the Marketing Authorization Holder;
    - Responsible for creating and maintaining a yearly roadmap to help prioritization of regulatory activities for International and Ireland.
- Acts as regulatory contact point for the export managers;
- In case of new licensing contracts that require regulatory activities, takes care of the appropriate drafting and signature of the regulatory agreements with Recordati partners and agrees on the regulatory action plan with the HQ team;
- Collaborate with HQ regulatory team on the lifecycle management planning of Marketing Authorizations related to International Pharma Sales BU, focusing on registrations in Latin America, Asia-Pacific, Africa, Middle East;
- Updates Regulatory Status for registered products (e.g. Marketing Status, Transfer of Ownership) related to International Pharma Sales BU;

Skills:

- Knowledge, at least in a general way, of pharmaceutical regulations applicable in Europe, Latin America, Asia, Pacific, Middle east
- Project management
- Knowledge of the CTD dossier and product information

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