

Regulatory Affairs Assistant 350

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Company: ProductLife Group

Location: Denmark

Category: business-and-financial-operations

About the job

We are seeking for a Senior Regulatory Affairs Assistant responsible for ensuring the delivery of regulatory activities performed on our regulatory affairs within the Nordic team :

About us

Group 10 Responsibilities

Execute on global regulatory strategy for established product(s) on continued post-approval product optimization, within relevant regions/countries and in line with the business strategy

Lead maintenance activities on established marketing authorisations to ensure regulatory compliance and delivery according to defined milestones and timelines

Prepare/contribute preparation of dossiers to support marketing authorization applications in close collaboration with Regulatory Strategy Lead

Ensure review of local Product Information before submission

Coordinate cross-product activities and strategic effort on regulatory activities as relevant

Support preparation of health authority interactions

Collaborate and liaise with regulatory affiliates and partners

Develop and maintain strong collaboration and communication with main internal stakeholders of Products/projects (Regulatory Strategy Leads, Supply, Global Patient Safety,

Commercial Operations and Medical Affairs)

Actively support regulatory intelligence, regulations and guidance activities to optimise cross-functional knowledge sharing. Proactively share knowledge and lessons learned

Represent Regulatory in cross functional settings and cross functional working groups as relevant

Group 13 Skills

Our preferred candidate has the following qualifications and experience:

University credentials in a relevant life science or medical discipline with a few years' experience working in regulatory affairs

Understanding of guidelines/legislation and awareness of global regulatory environment

Ability to work structured, independently and effectively across functions and geographies

Team player with good interpersonal skills including excellent communication, messaging and presentation skills

Fluent in English both written and spoken

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