

# Nordic Regulatory Affairs Manager Denmark

**On behalf of our client, a major pharmaceutical company, we are recruiting a Nordic Regulatory Affairs Professional / Manager to the company's Danish office just north of Copenhagen. The company has an attractive product portfolio and one of the best pipelines in the pharmaceutical industry in immunology, oncology, hematology and CNS.**

## **Responsibilities**

You will be taking responsibility for assigned regulatory-related activities, questions and relations for MRP and national approved products across the Nordic countries. Perform regulatory submissions following plan and updates from Regulatory Head office, enabling optimal implementation and maintenance. Keep overview of all regulatory-related activities for the assigned products on a Nordic basis, such as monitoring implementation of procedures, compliance and intelligence. Perform strategic and operational contacts with the Danish and the other Nordic Health Authorities. Ensure optimal compliance to both regulations and the company's own procedures. Review translations of texts/text changes (SPC, PL and package labelling) into Danish, for assigned products. Update databases with new approved texts (SPC, PL) for assigned products.

## **Qualifications and Experiences**

- You have a life science university degree, preferably a pharmacist, with at least 3 years of Regulatory Affairs experience in the Pharmaceutical Industry. Preferably you have worked in Regulatory Affairs in a head office and/or cross functionally in a local marketing company.
- You have excellent knowledge of the EU regulatory framework and the way it is implemented in the Nordic Countries.
- You have experience from a variety of Regulatory Affairs tasks such as working with centralized, MRP and nationally approved products.
- You have good knowledge of the scientific principles (CMC, clinical and non-clinical) applicable to pharmaceuticals.
- You are a native speaker of Danish and have proficiency in oral and written English.
- You are proficient in common computer programs (Microsoft Office and others).

**Please apply through [www.haegerpartner.se](http://www.haegerpartner.se)**

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