EURES ESPAÑA. Síguenos en y en

Senior Advisor Regulatory Affairs

Scandinavian Development Services

SDS works with drug development in the pre-approval phase (from the nonclinical phase to phase III). Our clients have a mix of NCE projects and projects with development of new formulations and/or new areas of use for established drug substances. In addition to regulatory experts, SDS has senior experts in a range of disciplines including CMC, DMPK, Toxicology, Clinical Pharmacology, Clinical Development and Biostatistics. Many clients use several disciplines from SDS which means that there is often an opportunity to work in teams with SDS colleagues. Even if you are the only consultant from SDS working with a particular client, you always have the possibility to use SDS colleagues as sounding boards.

A **Senior Advisor Regulatory Affairs at SDS helps our clients to define the overall regulatory strategy for their drug development projects from early phase (nonclinical) to MAA**. This includes **determining the product's classification** (regulatory framework), **legal basis and choice of procedure** as well as leading **interactions with regulatory authorities at national level (major countries across Europe), EMA and FDA as well as applications for ODD and PIP.** Other tasks include leading responses to authority questions in connection with CTAs/INDs, writing **drug development plans** (in cooperation with other disciplines as needed), looking into suitable reference products, MAA dossier planning etc.

There are today four Senior Regulatory Advisors in SDS and we often discuss complex project among us and divide projects/tasks according to experience and competence. This means that there will be flexibility with regards to which projects are allocated to whom depending on background and experience.

Profile

- University degree in Science
- Preferably at least 5 years' experience within Regulatory Affairs
- Experience from Drug Development
- Excellent communication skills (orally and in writing) in English
- Strong project management skills
- A collaborative mindset

Interested? Please contact us and send us your CV in English to:

Apply by sending your application to anna.torner@scanddev.se (con copia a eures.nordicos@sepe.es)

Consejos de utilidad:

Como preparar un CV y application letter "Swedish style": **http://goo.gl/mQXTBF** , y **http://goo.gl/O7r3Ej**