Remedica
FOR A HEALTHIER WORLD

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Registration Scientist (Non-Clinical and Clinical Summary expert)

Duties and Responsibilities

•Reviews the literature and identifies updates on the clinical and non-clinical data of the product.
•Prepares the clinical and non-clinical overviews for the initial dossier compilation.
•Prepares the clinical and non-clinical addendums needed for the renewals and variations of Marketing authorizations in the EU and the rest of the world.
•Assesses the risk benefit balance and concludes on the product's efficacy and safety.
•Prepares registration dossiers according to the requirements of each country.
•Replies to deficiency letters after submission until a marketing authorisation for the product is issued.
•Responsible for renewals and variations of marketing authorisations.
• Reviews of Drug Master Files.
•Checks newly prepared or modified labelling.
•Liaises with other departments and collects information.
•Replies to correspondence and follows up pending matters.
•Keeps informed of new regulations and guidelines relating to product and company registration.
•Learns and works with new programs/software that is required according to the guidelines for dossier preparation and that the company decides to implement.
•Informs Ministries of Health or representatives about registration matters.

Qualifications, Skills, Experience

- University degree in Pharmacy, Pharmacology or relevant field.
- Previous relevant experience of at least 3 years in the field of Regulatory Affairs or in relevant departments (Medical Writing, Research, Publication, etc.)
- Knowledge of the regulatory framework of the industry.
- Familiarized with platforms for Scientific Articles.
- Very good knowledge of English language.
- Strong analytical, communication, organisational skills.
- Computer literacy.

An attractive remuneration package depending on qualifications that includes 13th and 14th salary, Provident Fund, medical cover etc. is offered. Interested candidates should apply online through Remedica's website www.remedica.eu