Translation Manager

Job ID
REQ-10011591
Sep 02, 2024
Vereinigtes Königreich

Summary

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

The Role:

This role offers hybrid working, requiring 3 days per week / 12 days per month in our White City, London office.

As the Translation Manager you will be responsible for ensuring the availability and implementation of high-quality, regulatory-compliant translations of key product information documents, in 24 languages and to European Medicines Agency (EMA) deadlines. This activity is to support EU approvals via the centralised procedure (CP).

You will also share your regulatory and linguistic expertise and strategic advice to colleagues in Regulatory Affairs (RA) and other line functions, participating in related RA and company projects.

About the Role

Major accountabilities:

As a Translation Manager, you will be responsible for:

- Managing a quality focused and compliant translation process for key product information texts, approx. 70+ products for EU CP approval.
- Advising colleagues on regulatory and planning requirements, timely completion of translation requests and QC of all incoming translations. Liaise with EU RA Country Organisation and Global Program Regulatory Manager (GPRM) / Global Labelling Manager (GLM) colleagues on points of procedure and

any language issues that arise, addressing HA language reviewer feedback as required.

- Supporting submission of completed translations to EMA with supportive documentation and once approved, release of final approved files for implementation in the EU market.
- Supporting, for assigned projects, Language Services linguistic review and compliance of formatting to EMA requirements.
- Supporting teams in proactively proposing and negotiating with the EMA on complex regulatory procedures, working with EU RA and operational leads to manage responses from the authorities to reach agreement on final versions for submission.
- Ensuring the linguistic quality of English product information texts, performing thorough review of all text versions to ensure appropriate linguistic style and quality and compliance of formatting and terminology with EMA requirements.

Your experience:

- Bachelor's degree in one or more modern languages. A specific translation qualification is desirable.
- Excellent command of written and spoken English, as well as at least two other EU languages.
- Prior experience in a translation role, with good knowledge of CP, EMA Guidelines, and related business processes.

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