Senior Global Labelling Coordinator

Job ID
REQ-10011592
Jul 03, 2024
Reino Unido

Resumen

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 Global Labelling Coordinator you will be responsible for providing specialised support to RA Global Labelling Managers and the Head of Global Labelling related to the creation and maintenance of core labelling packages (including Core Data Sheets) for development programmes and marketed products including the coordination of global labelling activities according to regulatory requirements and company standards to ensure timely and compliant regulatory submissions worldwide. You will also provide support to the Language Services team to ensure the availability of high-quality, regulatory-compliant translations required for approvals worldwide.

About the Role

Major accountabilities:

- Support the creation and maintenance of assigned labelling projects to enable worldwide regulatory submissions.
- Independently coordinate the timely delivery of compliant documentation (Clinical Overviews, Non-clinical Overviews, SCE, SCS, PSUR, published literature, Expert CVs, Signature Pages, etc.) to support regulatory labelling submissions worldwide.
- Guide and support the Global Labelling Managers, RA Managers and cross-functional experts with the review of documents to ensure compliance with regulatory requirements and company standards, including formal QC.
- Maintain current information on the labelling project in planning tools and support compliance with required timelines.
- Coordinate planning and scheduling of topics and manage logistics of the Global Labelling Committee and joint labelling committee/safety board meetings including overall management of meeting minutes.
- Provide support during HA inspections and audits, such as compiling and archiving documentation, etc.
- Act as administrator and superuser for regulatory and labelling-specific databases.

- Support Translation Managers by creating regulatory-compliant (bookmarks, formatting, etc.) Word and pdf files for submission to the European Medicines Agency (EMA), adhering to required timelines.
- Independently prepare submission- ready files of amended translations for submissions involving minor, non-linguistic changes.
- Manage contact and delivery with external vendors, managing all aspects of workflow, payments for non-CP translation activities.
- **Your Experience:**
- Bachelor's degree preferred, with pharmaceutical industry experience preferably in Regulatory Affairs.
- Prior experience in translations management preferred.
- Good communication and negotiation skills.
- Fluency in English. Knowledge of other languages is desirable.
- Ability to work in a complex, cross functional working environment.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?: https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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Development
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Innovative Medicines
Ubicación

Reino Unido
Sitio
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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