Global Labeling Compliance & Project Lead

Job ID
REQ-10011598
Set 17, 2024
Regno Unito

Sommario

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!

About the Role

Major Accountabilities:

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

As Global Labelling Compliance Project Lead, you will be responsible for:

- The tracking, data mining, monitoring and reporting on the global implementation of safety related product information changes e.g. Core Data Sheet amendments and updates. This includes routine interaction and follow-up with Country (CO) and Regional Regulatory Associates and other cross-functional teams, including Quality Assurance (QA), Process Improvement & Excellence (PIE) and Technical Operations.
- Routine compliance reporting for global and local regulatory milestones of the Novartis safety label change process; support root cause analysis for any delays or non-compliance.
- Supporting internal Pharmacovigilance (PV) CO audits, interacting with the COs to ensure timely and current safety label change (SLC) compliance data and reports are provided.
- Supporting local and global PV inspections through preparation of requested SLC data and reports as required.
- Supporting the evolution and maintenance of the Novartis safety label change tracking tool (SALTO) and

related projects as a SALTO Super User.

- Providing input for process improvements, training manuals and materials, IT labelling projects and user testing.
- Supporting development of Novartis systems and company projects.

Your Experience:

- Bachelor’s degree required with relevant regulatory and/or technical experience gained in the pharmaceutical industry.
- Knowledge of Regulatory Affairs, specifically labelling regulations globally, labelling submission business processes and related tools.
- Proven knowledge of data analysis and reporting, excellent verbal and written communication skills, technical/IT skills and proven ability to be innovative and a creative problem solver with quality and compliance approach.
- Fluency in English as a business language required.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Divisione
Development
Business Unit
Innovative Medicines
Posizione
Regno Unito
Sito
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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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