Global Labelling Systems & Project Lead

Job ID
REQ-10011599
Juil 03, 2024
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

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: The Global Labelling Systems and Project Lead position is responsible for leading activities related to global labelling systems and tools, including system compliance activities and emerging IT projects. This ill also include US Compliance activities related to Structured Product Labelling (SPL), product drug listing, and US Labelling regulations and guidance. This role offers hybrid working, requiring 3 days per week / 12 days per month in our White City, London office.

About the Role

Major accountabilities:

- As subject matter expert for existing global labelling systems, you will lead activities related to system upgrades and functional improvements.
- Lead global labelling system projects, partnering with IT business leads and other business stakeholders to continually improve current systems and processes to support global labelling activity.
- Support Country Organisations as the lead on Labelling system and process compliance related activities such as, deviation reporting, system training, and process compliance.
- Be a Super User and main business contact for HQ-Global Labelling and Country Organisation end-users for relevant labelling systems and processes, training materials, manuals and SOPs.
- Support and contribute to a compliance and quality culture for Global Labelling systems/processes and provide assistance during audits/inspections when required.
- Lead all aspects of Structured Product Labelling activities including managing external vendor, resolving FDA SPL questions and validation concerns, and listing and delisting product NDC.
- Be responsible for conducting independent and comprehensive reviews of US PI labelling documents to ensure regulatory labelling compliance with US 21 CFR 201 and FDA guidance applicable to US labelling.
- Partner with Regulatory Affairs (or Reg-CMC) managers and perform final quality checks, confirming that

all FDA-approved labelling changes are accurately incorporated into internal master US product labelling documents prior to their being forwarded for use by other groups within Novartis e.g.: product packaging and US promotional materials/activities.

- Support proofreading activities of text for labelling of pharmaceutical products, ensure PLLR compliance within package insert and identify inconsistencies and errors, as needed.
- Prepare and review User Requirements Specifications and Functional Specifications, participate in formal system testing activities, as needed.

Your Experience:

- Bachelor's degree with fluency in English as a business language required.
- Experience in the pharmaceutical industry, or equivalent relevant experience involving a good working knowledge of Regulatory Affairs, specifically labelling business processes and related tools.

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.

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

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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10011599

Global Labelling Systems & Project Lead

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10011599-global-labelling-systems-project-lead*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://talentnetwork.novartis.com/network
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/GL-Systems---Project-Lead_REQ-10011599
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/GL-Systems---Project-Lead_REQ-10011599