Regulatory Affairs Manager - Precision Medicine (UK , Ireland or Austria)

Job ID
REQ-10011608
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 can be based in our White City, London office (hybrid working, 3 days per week) or the Novartis Schaftenau site in Austria.

As Global Program Regulatory Manager Precision Medicines you will be responsible for the successful implementation of strategic IVD regulatory plans and innovative regulatory solutions. You will achieve timely submissions/approvals and to adhere to regulatory requirements.

The GPRM Precision Medicines works with some independence to provide regulatory support including tactical and technical regulatory direction for projects within the Precision Medicine (PM) business of Novartis Development and Biomedical Research programs as they relate to IVDs; including tactical support to the PM associates to ensure execution of the Dx regulatory plans in line with the therapeutic global strategy and in collaboration with the RA lead on the Global Program Team. The GPRM coordinates, reviews, and may prepare reports for submission.

About the Role

Major accountabilities:

- Supports the global regulatory strategy and program for precision IVDs including CDx (e.g. US, EU, Japan, China), for premarket submissions, diagnostic partnering, FDA interface, regulatory policy, and

practice.

- Collaboration with the Project Management RA lead to facilitate integration of Dx regulatory strategy (aligned with drug/diagnostic co-development) and the coordination and implementation of regulatory readiness with other line functions within Project Management and drug RA.
- Ensures early diagnostic regulatory input for early development trials and late- stage clinical development to Technical and Clinical Development teams for precision diagnostics. Providing tactical support for the vision of PM RA and the action roadmap for activities with the regulatory bodies, to ensure Novartis' interests are reflected.
- Works directly with RA PM lead in establishing strategy and objectives for meetings with FDA CDRH and other Health Authorities (HA) for IVD devices.
- Facilitates the preparation, filing, and contributes to the preparation of summary documents, including coordination and planning for pre-Submission or other meetings with HAs. Develops, manages, and implements plans for timely response to HA requests and coordinates of any applicable follow-up activities.
- Develop the most efficient approach to preparation and submission of Dx regulatory dossiers, reviewing and contributing to global dossier on topics relevant to IVDs/CDx. Responsible for facilitating timely submission and approval of Dx submissions under the guidance of the RA PM lead and/or drug RA.

Your Experience:

- Science Degree (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent
- Experience in invitro diagnostics. medical devices or life sciences.
- Experience in diagnostics regulatory affairs ideal, with knowledge of molecular diagnostics a plus.
- Knowledge of drug development and regulatory affairs requirements, and familiarity with regulatory issues (EU IVDR, US LDT), challenges associated with Drug/ Diagnostic co-development, and Companion Diagnostics
- Strong interpersonal skills and experience working in a complex, cross functional organization.
- Fluency in English.

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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Global Drug Development
Business Unit
Innovative Medicines
Standort
Vereinigtes Königreich
State
London
Site
London (The Westworks)

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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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