Regulatory Compliance Project Specialist

Job ID
REQ-10023412
Nov 06, 2024
Ireland

Summary

Support the day to day activities of the European MAH, Novartis Europharm Limited fulfilling requirements of the EMA and EU country organizations.

About the Role

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 in our Dublin office.

As a Regulatory Compliance Project Specialist you will support primarily the day-to-day activities of the European MAH, Novartis Europharm Limited, fulfilling requirements of the EMA, HPRA and EU country organizations. Support with administrative activities and processing of correspondence received from EMA and other Health Authorities. Responsible for monitoring of QA and RA mailboxes and management of any requests and / or notifications required to be completed. Driving compliance within the Department to ensure inspection readiness in accordance with Novartis and local HA requirements. Monitoring of licence maintenance systems and follow-up of marketing authorizations, licence maintenance and life cycle management.

Key Accountabilities:

- Ensure good knowledge and compliance with EU and national regulations (Dir 2001/83/EC and *SI 541/2007*) compliance with local codes of conduct for related CO activities -
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products

according to local processes and within 24 hours of receipt -
- Ensure proper archiving of all documents submitted to the Health Authorities and related correspondence
- Act as system super user or subject matter expert for certain projects.
- Ensure accurate and timely data update of regulatory compliance database (e.g. DRAGON, REDI-GO), supports with compliance metrics.
- Support development and maintenance of relevant local and global SOPs.
- Ensure effective collaboration with internal & external stakeholders (incl. HA, QA, RA, SCM) in relation to supply and/or quality topics

Your experience:

- BSc. In Life Sciences degree is minimal requirement.
- Successful experience as Regulatory Affairs and/or Quality Assurance experience.
- Well-organized, excellent project management and strong analytical skills
- Excellent verbal and written communication and negotiations skills

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

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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

Division
Development
Business Unit
Innovative Medicines
Location
Ireland
Site
Dublin (Country President Office (CPO))
Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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