Senior Regulatory Affairs Coordinator

Job ID
REQ-10011574
Jul 05, 2024
United Kingdom

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 offers hybrid working, requiring 3 days per week in our London office. The Regulatory Senior Coordinator provides high quality and timely operational and compliance support on assigned programs and/or activities through the development, registration and post approval phases. You may also act as a subject matter expert for certain RA systems or processes. This role works under the supervision of the respective regulatory affairs program team and/ or team lead.

About the Role

Major accountabilities:

- Provide operational regulatory support for a portfolio of programs, Independently coordinating with other groups within RA to finalize and ensure timely dispatch of Health Authority submissions as aligned with assigned program RA sub-teams.
- Contribute to or lead preparation of assigned Module 1 documents including forms and cover letters with oversight of the RA program lead(s). Support RA sub-team for clinical trial related activities (CTA forms and tracking, transfer of obligations submissions, drug shipment ticket review, etc.).
- Independently manage assigned regulatory compliance and maintenance activities for clinical trial, registration and post-approval regulatory activities.
- Ensure tracking and update of relevant regulatory information in Novartis compliance systems and trackers as provided by RA sub-team representatives.
- May act as super-user and/or subject matter expert for selected topics or systems.
- In some lifecycle management groups, support regulatory activity with a focus on divestment, portfolio rationalisation, procurement of samples and certificates, and new product planning.

Your Experience:

- Bachelors degree preferred.

- Pharmaceutical industry experience, ideal in regulatory operations.
- Good interpersonal skills and experience working in a complex, cross functional organization.
- Fast, flexible and focused on timely delivery. Compliance and quality mindset.
- 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.

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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Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
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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2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://talentnetwork.novartis.com/network
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