Global Program Regulatory Director

Job ID
REQ-10011577
Set 19, 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 join us in reimagining new medicines together!

The Role:

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

As Global Program Regulatory Director, you will provide global leadership throughout the lifecycle of a development and/or marketed product program(s). Your experience will ensure that input from global HAs, regional and functional collaborators is collated to build a coherent, global regulatory strategy which fulfills the target product profile and portfolio objectives.

You will also be responsible for identifying regulatory opportunities, mitigate against potential issues and ensure the execution of regulatory strategy across regions. In addition, you will lead global regulatory sub-team(s), share your regulatory and development expertise, and represent the RA function on cross functional initiatives and committees.

About the Role

Major accountabilities:

Regulatory Strategy & Submissions

- With multiple stakeholders, develop, document and communicate high quality global regulatory strategies and HA interactions to achieve business objectives.
- Evaluate and communicate potential global regulatory opportunities and risks, developing mitigation strategies

- Leverage regional expertise in executing global regulatory strategy, and HA engagement.
- Provide strategic regulatory input into analysis and interpretation of scientific data, to key documentation,
- Leverage scientifc knowledge and acumen in the analysis, interpretation and communication of data to colleagues. Lead interactions with Regulatory Affairs and Development Unit management and external consultants, for input to regulatory strategies.
- Accountable, in conjunction (with regulatory labelling) for maintaining Novartis core product information documents though product life cycle.
- Contribute to any BD&L Due Diligence activity
-

Regulatory Excellence & Compliance

- Ensure compliance with global regulatory requirements and adherence to regulatory internal policies and processes, coordinating regulatory compliance activities at a global level.
- Provide support as needed for non-project related excellence activities.

People

As an effective matrix leader, provide feedback and mentor team members, line functions and sub- teams. Working with line managers, you will provide opportunities for team member growth and development, leading by example acting as a role model for Novartis values and behaviours.

Your Experience:

- Science based bachelor's or master's degree. Advanced degree desirable.
- Significant regulatory and pharmaceutical development experience, across Phases I-IV.
- A track record of working with HA guidance and feedback, discussion and negotiations; post marketing/ brand optimization strategies and regulatory operations.
- Proven leadership success across a broad range of regulatory and pharmaceutical development activities.
- Strong interpersonal skills and experience working in a complex, cross functional organization, navigating complexity and leading cross function teams.
- 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

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
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-10011577

Global Program Regulatory Director

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10011577-global-program-regulatory-director*

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://www.novartis.com/careers/benefits-rewards
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/Global-Program-Regulatory-Director_REQ-10011577
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/Global-Program-Regulatory-Director_REQ-10011577