

Manager Regulatory Affairs Process Excellence

Job ID

REQ-10010708

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!

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

In this role you will be responsible for the development and implementation of regulatory quality processes and procedures, aligning with global RA and other functions. You will also support the implementation of initiatives within RA to support a quality system. This involves establishing and maintaining a comprehensive set of clear, consistent RA policies and procedures that align with global functions, both within and external to RA, and across Novartis Business Units.

About the Role

Key Accountabilities:

- You will oversee and manage business processes and their links to systems, and own certain business processes within the assigned business process area.
- Drive and coordinate with business process owners, the end-to-end process strategy within respective area to ensure alignment within and outside RA.
- Drive and implement continuous process improvement strategies or closure of process gaps across process area. Point of contact for other functions outside RA for process alignment and new process implementation within respective area.
- Support quality and consistency of RA regulatory compliance activities in assigned region through implementation of new processes, policies, metrics and appropriate training, and ensuring data compliance in the global RIM system.
- Partner with Region Head, Sub-region Heads, and Subject Matter Experts from assigned region to implement and track training for policies, processes and procedures.

- Participate in cross-functional process improvement projects to represent the function; help to identifying resources from the function to support cross-functional projects
- Support the preparation of the RA organization for internal global audits including CAPA management, collaborating with QA to prepare RA/ Country Organisations for external inspections at HQ including CAPA management.
- Work with Director RA Process Excellence to address potential quality issues and emerging compliance concerns and recommend solutions, providing backup support, as needed

Your experience:

- Life science degree.
- Pharmaceutical industry experience, in Regulatory Affairs.
- Demonstrable experience in working knowledge of SOPs and compliance.
- Good interpersonal, negotiations and communication skills.
- Experience working in complex global environments and cross functional teams

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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TEst Hello

Division

Global Drug Development

Business Unit

Innovative Medicines

Standort

Vereinigtes Königreich

State

London

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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expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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