Senior Manager Regulatory Affairs Process Excellence

Job ID
REQ-10010714
Jul 03, 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! This role offers hybrid working, requiring 3 days per week in our White City, London office. In this role you will be responsible for leading the development and implementation of enhanced regulatory quality processes and procedures, aligning with global RA and other functions. You will also support 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

Major accountabilities:

- 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, and harmonized implementation.
- Proactively 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.
- Enhance 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 trainings for policies, processes and procedures.
- Participate in cross-functional process improvement projects to represent the function; identify resources from the function to support cross-functional projects
- Prepare the RA organization for internal global audits including CAPA management
- Collaborate with QA to prepare RA for external inspections at HQ including CAPA management
- Support countries within assigned region with internal audit and external inspection preparation and

CAPA proposals as needed.
- Manage quality incidents/deviations in the appropriate system together with global RA functions according to timelines.
- 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,
- Demonstrable experience in EU regulatory and drug development, working knowledge of SOPs and compliance.
- Experience working in complex global environments and leading cross functional teams.
- Project management experience.
- Excellent negotiaton, communication and interpersonal skills.
- 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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