Regulatory Affairs Systems & Strategy Manager

Job ID
REQ-10011619
Sep 02, 2024
Vereinigtes Königreich

Summary

Our Regulatory Operations Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are simplifying 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 in evolving the future of Regulatory Operations and to give our patients 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 person in our White City, London office. Ad-hoc working hours to overlap the US as required.

In this position you will be responsible for the development, implementation, and support of regulatory systems for the Novartis global product portfolio.

You will be an individual contributor in the Regulatory Systems & Strategy Group

About the Role

Major accountabilities:

- You will act as system owner deputy for Vital/ GXP applications, providing first line system and end user support e.g. incident and service request management.
- Liaise with GDD colleagues on changing regulatory requirements and related business process, to ensure knowledge transfer to IT business partners for system enhancements.
- Prepare User Requirement and Functional Specifications, Administrative Procedures and Working Instructions to support system implementations.
- Be a key business contributor in Technology initiatives e.g. system upgrades, Validation, implementations, and functional enhancements, overseeing and supporting PQ Testing and Application

Variations.

- Develop, implement and support innovative regulatory strategies and life cycle management of RA systems, managing global projects and initiatives relating to regulatory applications and business processes.
- Support user training of RA end users and IT partner. Mentor junior associates.

Your Experience

- Degree educated in a relevant discipline with systems related experience in pharmaceuticals (ideally Regulatory Operations)
- Effective interpersonal and customer service skills.
- Ability to work across multiple levels within a complex organisation, team player and collaborative partner.
- Knowledge of worldwide Health Authority submission formats, pharma drug development process and associated document requirements is desirable.

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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