Global Regulatory Affairs Manager - Manufacturing Production Transfer

Job ID
REQ-10011606
Nov 21, 2024
Reino Unido

Resumen

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 a week / 12 days a month based in office.

Job Purpose:
Responsible for managing with limited supervision all regulatory maintenance activities of an assigned portfolio with a focus on production transfer projects. The role will represent regulatory affairs and serve as the single point of contact for cross-functional project teams, providing strategic direction on production transfer projects, driving and monitoring progress and deliverables.

About the Role

Major accountabilities:

- Manage manufacturing transfer projects and represent regulatory affairs in cross-functional teams
- Ensure with limited supervision that maintenance submissions are prepared on time and in compliance with regulatory regulations, guidelines, and in line with Novartis processes and system requirements.
- Responsible for providing strategic regulatory input for the preparation of cross functional deliverables (e.g. variations/supplements, renewals, annual reports)
- Uses regulatory expertise and portfolio knowledge to identify issues, gaps, and tradeoffs to avoid/minimize delays and to achieve timely submission and approval.
- Manages timely response to HA queries and contribute to preparing strong justifications to address

regulatory gaps
- Responsible for appropriate entering of product specific attributes in compliance database and applicable RIMs
- Manage preparation and finalization of documents for HA interactions
- Contribute to non-project related initiatives focused on productivity, continuous improvement, and automation
- Support other associates within Regulatory Affairs by providing training on specific topics and act as a Subject Matter Expert

Your Experience:

Education:

(required and preferred)

Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.

Languages:

(required and preferred)

Fluency in English – Additional language is an asset.

Experiences & Skills:

- 4+ years of knowledge and experience in regulations, guidelines and regulatory processes for regulatory maintenances activities
- Regulatory experience in manufacturing site transfers
- Experience with regulatory submission and approval processes
- Experience working and delivering results in a global/matrix environment and with cross- functional teams
- Planning, execution, reporting, regulatory review, compliance and submission experience
- Ability to contribute to process improvements and operational excellence initiatives
- Reliable, timely, accurate and proactive communication as appropriate.

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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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

División
Development
Business Unit
Innovative Medicines
Ubicación
Reino Unido
Sitio
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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