NOVARTIS

Global Regulatory Affairs Manager - Manufacturing Production Transfer

Job ID
REQ-10011606
Nov 21, 2024
United Kingdom

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

Role Requirements

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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

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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