NOVARTIS

Senior Regulatory Affairs Manager

Job ID
REQ-10015715
Μαρ 25, 2025
United Kingdom

Περίληψη

The Senior Regulatory Affairs Manager is proficient in all aspects of submission, approval and life-cycle management of assigned Marketing Authorisations (MAs), providing effective regulatory support to the UK and global organisations. They also acts as a mentor for Regulatory Affairs Managers.

This is a hybrid role - there is a requirement of a minimum three days on site in the London office.

About the Role

Major Accountabilities

Responsibilities for a number of MAs for which the following activities will be required:

Brand

- Works closely with global and local colleagues to advise and agree on regulatory strategy and data requirements.
- Critically evaluates submission packages in line with regulatory requirements in order to eliminate deficiencies prior to construction and submission of MA applications within agreed timeframes.
- Monitors and influences assessment process to expedite and optimise the outcome of their submissions. Drives negotiations with MHRA to ensure best possible outcome which may include for example, optimal product labelling or assurance of supply continuity and delivery of their commitments and deadlines.
- Ensures communication of any regulatory changes to the business as necessary to support license compliance.
- Works closely and swiftly with cross functional teams to address critical issues eg batch recall or other batch release issues.
- Submission and maintenance of official local drug information, including Patient Information Leaflets, SmPCs, packaging texts, RMPs and their Educational Material.
- Independently manages new MA submissions eg Scientific Advice meetings, attendance at launch meetings, pre-vetting materials and stock readiness.

Customer

- Provides regulatory advice to global and UK business on all aspects of maintenance work including advice on data requirements, strategy, medicines legislation/guidelines, to ensure informed decision making and best chance of optimal assessment timing and outcome.
- Contributes to regulatory strategy, by participation in RA Subteams, providing assistance to the global RA representative as appropriate.
- Provides regulatory advice and support for divestment and in-licensing opportunities.

- Proactively builds relationships externally (MHRA) and internally (BF, MI, TechOps, Patient Safety, Global colleagues), so that business needs are met.
- Active participation in Business franchise meetings providing regulatory advice and support to the UK teams.

People

- Acts as a mentor for Regulatory Affairs Managers and occasionally deputise for Regulatory Affairs Business Franchise Lead.
- Assists in coaching and developing less experienced members of the team (professional/interpersonal skills).
- Contributes to the continuous process improvements and inspection readiness for both internal process reviews/audits and HA inspections for GxP.
- Self initiates personal development opportunities.

Minimum Requirements:

- Life Science Degree or other relevant education.
- Broad range of regulatory experience, encompassing CMC, Clinical and Commercial aspects in the ethical pharmaceutical industry

Languages :

- 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

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Τομέας
Development
Business Unit
Innovative Medicines
Τοποθεσία
United Kingdom
Τοποθεσία
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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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