Regulatory Affairs Manager / Specialist

Job ID
REQ-10040437
Feb 21, 2025
Dinamarca

Resumen

LOCATION: Copenhagen, Denmark
ROLE TYPE: Hybrid working (3 days per week in the office)

As a member of the Regulatory Affairs (RA) team in Copenhagen, you will get the opportunity to work in a dynamic, agile team who has a common goal to bring our medicines to patients.
We are looking for a Regulatory Affairs Manager or alternatively a Specialist for human medicines preferable with more than 3 years of experience and with the desire to lead projects. Novartis Healthcare A/S has a wide portfolio that includes orphan drugs, biologics, oncology therapeutics and advanced therapies like gene therapy and radio ligand pharmaceuticals. You will be responsible for all regulatory activities in line with global and local strategy for a defined part of the products.

About the Role

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This role will focus on various project locally and globally and we expect this role to take the lead. You will be part of cross-functional teams and have close collaboration with other line functions.

In addition the job will include planning and execution of regulatory strategy for submissions to health authorities and collaboration with Novartis Global Regulatory Affairs.

Your responsibilities include, but are not limited to:

- Lead regulatory project both locally and globally
- Support and drive interaction with Global Regulatory affairs, and local functions like Supply Chain, QA, Market Access, Marketing (project and product teams) and Medical to best bring our medicines to patients according local and global strategy.
- Clear communication of complex regulatory strategies with both Danish Medicines Agency and internal stakeholders.
- High quality and timely Regulatory Affairs input to planned filings and approvals of new marketing authorizations (MA) and line-extensions.
- Maintain established products according to global and local regulatory plans and procedures: Translation of a Summary of Product Characteristic (SmPCs) and leaflets within given timelines and update regulatory databases.

Minimum requirements

- University degree (Master level or more) in medical, pharmaceutical or biological science.

- Preferably more than 3 years of regulatory experience in the pharmaceutical industry or with Health Authorities.
- Fluent in Danish (oral and written). Excellent medical English and excellent medical Danish.
- A mind-set of curiosity, learning agility and collaboration

The closing date for applications is 14th March 2025.

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

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

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

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División
Development
Business Unit
Innovative Medicines
Ubicación
Dinamarca
Sitio
Copenhagen
Company / Legal Entity
DK06 (FCRS = DK006) Novartis Healthcare A/S
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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