NOVARTIS

Regulatory Affairs Medical Device Manager (Schaftenau, Austria)

Job ID
REQ-10011610
Jun 28, 2024
Austria

Summary

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:

Ths role will be based at the Novartis Schaftenau site in the Tyrol, Austria.

As Global Program Regulatory Manager Medical Devices & Drug/Device Combination Products you will independently provide strategic and operational global medical device regulatory direction and documentation for projects/products. This includes those projects/ products in development, registration and approval/post approval. You will make informed regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals.

About the Role

Major accountabilities:

- You will support the global Medical Device & Precision Medicine regulatory strategy with a focus on innovation, maximizing business benefit balanced with regulatory compliance.
- Lead, support and implement all global Regulatory Affairs Medical Device (RA MD) submission activities for assigned projects/products, identifying the required documentation for timely global submissions to deadline.
- Author and/or review high-quality RA MD documentation for HA submission, applying agreed RA MD Global regulatory strategies, current regulatory trends and guidelines.

- Proactively communicate RA MD regulatory strategies, risks and key issues throughout the life cycle, to project teams and other stake holders. Represent department in cross-functional project teams as appropriate.
- Lead, prepare and communicate RA MD Risk Management Assessments, contingency plans, and lessons learned on major submissions and escalate as appropriate.
- Initiate and lead Health Authority interactions and negotiations as appropriate; setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans.
- Establish and maintain a single point of contact with global HAs.
- Represent department on due diligence teams for in-licensing and divestment opportunities.

Your Experience:

- Science Degree (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology,Biology) or equivalent
- Medical device & Drug/Device Combination Products regulatory affairs experience, in the pharmaceutical and/or medical device industry.
- Good knowledge and experience in medical device & Drug/Device Combination Products regulatory submissions and approval processes, with understanding of product development life cycle.
- Ability to critically evaluate data from a variety of sources, work in interdisciplinary teams and prioritise activities, timelines and workload.
- Strong interpersonal skills and experience working in a complex, cross functional organization.
- Fluency in 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

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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Division
Development
Business Unit
Innovative Medicines
Location
Austria
Site
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Alternative Location 1
London (The Westworks), United Kingdom
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Adjustments for Applicants with Disabilities

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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EEO Statement :

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