Global Head RA Medical Devices

Job ID
REQ-10030806
Nov 22, 2024
Reino Unido

Resumen

The Global Head of RA Medical Devices is responsible for leading the RA Regulatory Device team that is accountable for the development and implementation of the regulatory strategy for all Novartis Medical Devices, medical device components for Combination products and Software-as-Medical Device.

The Global Drug Development therapeutic areas included are: Ophthamology, Respiratory/Allergy, Neuroscience, Cardiovascular/Renal/Metabolism, Immunology/Hepatology/Dermatology, Oncology and Hematology as well as the license maintenance of the entire Novartis Marketed Medical Device Product Portfolio.

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!

About the Role

This role offers hybrid working, requiring 3 days per week OR 12 days per month in our White City, London office.

Key Responsibilities:

- Define an RA Medical Devices vision and strategy to optimize business processes, organizational structure, collaborative culture, and strong learning environment. Provide leadership and oversight for strategic and technical regulatory support in the compilation of all medical device dossiers as required by global health Authority agencies to support the approval and/or maintenance of the product license.
- Provide leadership and oversight for the strategic and technical regulatory direction from Proof of Concept, development through global registration for all Novartis Medical Devices, medical device components for Combination products and Software-as-Medical Devices in collaboration with the respective GDD cross functional teams.
- Oversee high-quality device documentation during development and product registration that are accurate and compliant with global regulatory requirements.
- Oversee high-quality device documentation for marketed products to ensure rapid registrations of product changes or license maintenance assuring congruency and regulatory compliance.
- Ensure timely coordination of all necessary regulatory activities within the company to ensure timely compliance with regulatory submission requirements.
- Lead the company negotiations with key health authority agencies during development, registration, and

product lifecycle activities to resolve regulatory issues and/or negotiate Medical Devices, medical device components for Combination Products, Software-as-Medical Devices approvals with superior product labeling.
- Provide expertise and direction for regulatory requirements of notified bodies and various authorities, as well as input to the preparation of development documents (e.g., technical file), development of the regulatory strategy for the submission of new projects, change notifications, variations etc., and input to general development concepts.
- Liaison with Notified Bodies and Regulatory Authorities as needed to gain Medical Device product approval or maintenance of an existing product license.

Essential Requirements:

- Fluency in English.
- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph. D, PharmD).
- Experience in Medical Device industry.
- Regulatory GTAL or equivalent level of experience on multiple/complex projects.
- Oversight of multiple MAA, NDA/BLA, 510K, PMA submission(s) and product approvals.
- Excellent verbal and written communication skills.
- Extensive experience in leading HA negotiations with US, EU, Japan, and China Health authorities.
- Experience with Due Diligence evaluations to support licensing activities.
- Team management experience with cross functional responsibilities.
- Proven ability to analyze and interpret efficacy and safety data.
- Must be a 'problem solver' with demonstrated ability to provide strategic direction at an advanced level.
- Demonstrated innovator in developing regulatory strategies.
- Demonstrated ability to manage and develop associates.
- Demonstrated ability to successfully utilize organizational structure and processes.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

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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