NOVARTIS

Senior Regulatory Affairs Associate

Job ID
REQ-10028495
Nov 05, 2024
Australia

Summary

Internal Role Title: Senior Regulatory Affairs Associate

Location: Sydney, Australia #LI-Hybrid

We bring life-saving and life-changing medicines to patients by determining the optimal regulatory pathway to accelerate the approval process whilst ensuring we achieve the broadest label necessary so that as many patients can access our treatments.

We do this by collaborating closely with Novartis global colleagues, our local brand teams and external health authorities.

We are a highly experienced team that is goal orientated, continues to learn, leverages off each other's experiences and we look for opportunities to do things differently.

About the Role

Key Responsibilities:

- Submit NCE/NBE and line extensions to AU and NZ health authorities as per business alignment
- Gap analysis of submission packages and develop the submission strategy which may include HA meeting
- Maintain allocated products for example CMC and packaging changes which includes forward planning to avoid shortages
- Minor PI updates (SRR or Type J)
- Prioritize tasks based on business criticality. Actively participate in brand team meetings and review promotional material
- Contribute to consultations, internal processes and projects. Communicate effectively (written and verbal) to a range of stakeholders
- Demonstrate and encourage behaviors that promote a positive, collaborative team culture. Provide constructive feedback and mentoring to team members to help build capabilities.

Essential Requirements:

- Science, Pharmacy, Medicine or other relevant degree. Postgraduate qualifications would be an advantage
- Senior RA associate with proven track record of innovation, technical competence and successful business outcomes or 6+ years' experience as an RA associate. Australian experience preferred

although RA experience in US, EU or Canada would also be considered
- Broad AU regulatory experience dealing with and solving a broad range of complex business and/or regulatory issues.
- Will consider candidates with prior regulatory experience working in following jurisdictions: Singapore, Canada, US, EU but relocation is not supported.

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

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

Division
Development
Business Unit
Innovative Medicines
Location
Australia
Site
New South Wales (NSW)
Company / Legal Entity
AU04 (FCRS = AU004) AU Pharma Pty 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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