Senior Regulatory Affairs Associate

Job ID
REQ-10055203

6月 17, 2025

Australia

摘要

#LI-Hybrid
Location: Sydney, Australia

This role is based in Sydney, Australia. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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.

Commitment to Diversity and Inclusion / EEO paragraph:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams

representative of the patients and communities we serve.

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

部门
Development

Business Unit
Innovative Medicines

地点
Australia

站点
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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