Senior Regulatory Affairs Compliance Associate-12 months contract

Job ID
REQ-10012207
Juli 28, 2024
Australien

Summary

We are looking for an expert pharmaceutical professional to join our team with the focus of Regulatory Affairs Operational Excellence. We need a creative and curious individual, who can look at our systems with a different lens, who is empowered to find ways to make them even more effective and efficient.

The key responsibility of this role is to ensure regulatory compliance in accordance with Novartis processes, procedures and systems as well as relevant Australian and New Zealand legislation and guidelines.

About the Role

Internal Role Title: Senior RA Compliance Associate (12 months contract)

Location: Sydney, Australia #LI-Hybrid

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.

Key Responsibilities:

- Handle regulatory information using Novartis' Regulatory Information Management (RIM) tools end- to-end - handling new entries, crafting variations, updating entries and reflecting approved changes.
- Ensure key operational trackers are kept up-to-date and that information is entered with consistency by RA Associates
- Handle department's RIM mailboxes and triage incoming data packages (CDS, CMC, PSURs, RMP and relevant communications within the organisation), prioritize activities for Teams
- Validate pre- and post-approval activities to ensure compliance with health authority (i.e. TGA and Medsafe) requirements are met.
- Supervise GMP clearance requirements, handle GMP clearance applications and maintain compliance.
- Be responsible for change control process from Regulatory Affairs perspective, collaborating with relevant business units. Perform and respond to Global Regulatory Compliance Checks and liaising with local relevant department on resolving supply issues.
- Conduct risk analyses, develop effective procedures and tracking tools. Support training of new associates and onboarding into compliance related systems and tools
- Provide assistance and support in preparation for and during the course of internal and external audits and inspections of RA operations.

Essential Requirements:

- Tertiary qualified – Pharmacy or Science (majoring in a life science ideally). A relevant postgraduate qualification would be considered an advantage.
- Proven experience in the pharmaceutical or healthcare industry, academia or a field associated with well-developed compliance standards (legal, Corporate Compliance, QA, Clinical Trial), ideally in Regulatory Affairs
- Strong understanding of quality systems and local regulations.
- A detailed working understanding of regulatory compliance as it relates to business operations
- Apply good documentation and record keeping practices.

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:

We are 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

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Division
Development
Business Unit
Innovative Medicines
Standort
Australien
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
Temporary (Fixed Term)
Shift Work
No
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