U NOVARTIS

Regulatory Affairs Business Architecture & Data Integrations Capability Lead

Job ID REQ-10049715

6月 03, 2025

USA

摘要

As a member of the Regulatory Affairs Data Strategy and Management Platform, the Business Architecture & Data Integrations Capability Lead owns and oversees all aspects the Capability and contributes to the overall Platform strategy delivering business benefits, harmonization and continuous improvements.

The Business Architecture & Data Integrations Capability lead is accountable for the overall cataloging of business data, defining data model requirements and Data Integration requirements. This role requires a deep understanding of regulatory data and how it flows through systems across the regulatory landscape, e.g. Data Lakes, Enterprise Data Warehouses, 3rd-party data integrations, regulatory technology solutions, etc. and how data flows in the registrations ecosystem across the Novartis Enterprise.

About the Role

Key Responsibilities:

- Lead a team to ensure alignment with organizational goals and business priorities related to Business Architecture and Data Integrations
- Support the strategic vision for the Data Strategy and Management Platform, from a Capability level
- Define, prioritize, and deploy an integrated Capability roadmap working in close collaboration with relevant stakeholders and DDIT partners, ensuring alignment with the Data Strategy and Management Platform, Development and Enterprise data and technology strategy roadmaps
- Represent the Capability in digital governance boards and leadership meetings across the organization
- Represent the Capability in digital networks, externally (e.g. across Industries) as needed
- Oversee integrations with Products underlying the Capability
- Build and maintain collaborative and productive partnerships within the Capability and the Platform, and with relevant stakeholders to achieve business priorities.
- Oversees the cataloging and technical controls of the RA Data model in line with Novartis strategy and Industry Standards, business data architecture, Logical data model, Integration requirements, data model requirements and approves and secures data governance policies and processes

Essential Requirements:

- Bachelor 's degree, master 's; Advanced degree in life science, pharmaceutical, technology or data science preferred.
- 8+ years of relevant industry experience
- Strong understanding and direct relevant experience with the Business Architecture and Data Integrations landscape of pharmaceutical regulatory affairs and Regulatory Information Management
- Practical experience in technology process requirements and business administration management
- Deep knowledge of regulatory standards and structured data submissions
- Strong network and exposure to the external environment and ability to represent company and influence in Trade organizations (e.g., EFPIA, PhRMA), International Organizations (ISO), and collaboration with regulators (e.g. ICH, EMA SPOR), or consortiums
- Strong strategic problem-solving skills and ability to navigate un-charted territory without clear precedent
- Experience presenting/speaking at a senior management level with a proven track record of effectively communicating complex initiatives
- Demonstrated leadership in driving risk assessment and mitigation, clear strategic thinking, prioritization, maintaining awareness of business impact
- Excellent verbal and written communications

Desirable Requirements

- Strong negotiation skills
- Broad experience in quality assurance/compliance, computer system validation within the

pharmaceutical/biotech arena, the management and conduct of audits, stakeholder focus, and strong knowledge of regulatory requirements

The salary for this position is expected to range between \$132,300 and \$245,700 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you

need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to <u>us.reasonableaccommodations@novartis.com</u> or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门 Development

Business Unit Universal Hierarchy Node

地点 USA

状态 New Jersey

站点 East Hanover

Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area Research & Development

Job Type Full time

Employment Type Regular

Shift Work No

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