Regulatory Affairs Data Governance and Quality Capability Lead

Job ID
REQ-10049717

6月 04, 2025

USA

摘要

As a member of the RA Data Strategy and Management Platform team, the Data Governance and Quality Capability Lead is responsible for independently driving and implementing data standards and strategies for emerging data-driven HA requirements, and relevant systems’ governance processes across all domains and functions, in support of the NVS global product portfolios to improve data maturity according to RA business objectives.

The Data Governance and Quality Capability Lead is accountable to drive harmonization and continuous improvement of Data Governance related activities and initiatives in close alignment with internal and external stakeholders to improve data maturity according to RA business objectives. The Capability Lead will drive the Centralized Data Quality Management culture in Regulatory Affairs and ensure Data Quality consistency, correctness and completeness across all applicable RA systems and platforms.

About the Role

#LI-Hybrid

Key Responsibilities:

- Lead a team to ensure alignment with organizational goals and business priorities related to Data Governance and Quality
- Serve as Data Governance and Quality Capability Lead for RA and as the point of contact for GDD Data team
- Lead RA cross-functional teams to develop data roadmap, in alignment with cross-domain Data Governance boards
- Accountable to create and implement data management and quality strategy
- Expert contributor to influence draft guidance on data standards / specifications / implementation from Health Authorities and Trade Organizations. Prepare interpretative analyses about impact on internal data and digital processes.
- Collaborate with Development Data Management and DDIT partners to develop and implement RA Data Governance structures (boards) and policies, ensuring involvement of Business Process Owners (BPOs) and business SMEs.
- Oversee vendors at the Capability level, in collaboration with IT and the External Partnerships Teams
- Manage Data Governance and metrics reporting on data operating model throughout the DQM lifecycle
- Responsible for configuration, decision making and outcome, impacting the capability, with involvement of relevant Business Process Owner(s), business SMEs and stakeholders

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 Data Strategy and Management landscape of pharmaceutical regulatory affairs and Regulatory Information Management
- 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
- Advanced knowledge of worldwide evolving external data standards as well as drug registration and approval processes and related document format requirements and in-depth knowledge of good Regulatory compliance and intelligence practices, policies, procedures
- Strong understanding of regulatory requirements and structured data submissions standards and initiatives
- Excellent business writing, communication and effective presentation skills.
- Extensive experience leading meetings, driving change and cross-functional teams

Desirable Requirements:

- Strong strategic problem-solving skills and ability to innovate, analyze and navigate un-charted territory without clear precedent, ability to troubleshoot effectively, accurately and independently.
- Strong negotiation skills

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? 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

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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 us.reasonableaccommodations@novartis.com 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.

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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
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Employment Type
Regular

Shift Work
No

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