

# **RA Product Lead**

Job ID REQ-10065544

12月 02, 2025

India

## 摘要

As a member of a Capability team within the Data Strategy and Management & Platform Operations, the Product Lead contributes to the strategic vision of Regulatory Affairs and supports the digitalization of RA, by being responsible for one or several data group(s) and/or product(s) underlying the capability.

The Product Lead, Data Strategy and Management, is accountable to ensure that the Data Group(s) and/or Technology Product(s) strategy delivers business benefits, drives harmonization and Support NRV in BA Capability.

#### About the Role

Major accountabilities:

 Data Group and BA Product responsibility: Act as data group and/or product owner; manage development & design and success and maintain data and product experience in line with business needs.

- Responsible for data and product support, adoption, communication and training, incl. continuous end user support, ensure system performance (managed by IT). Is aware of the data and/or product-related technology & regulatory landscape, and evolving trends (externally and internally)
- Acts as a data quality lead and functional change lead at the data group and/or product level to drive communication and training, facilitating alignment and documentation of data elements under governance, as well as adoption of standard terminologies across systems
- Accountable for codification of rules in Data Quality tool, establishment of centralized master and reference data management (MDM and RDM), and work with data stewards and owners to implement good data management practices in RA
- Accountable for the development and maintenance of business data architecture, logical data models, integration requirements, and data model requirements. Accountable for ensuring compliance with data governance policies and processes
- Roadmap Development: Definition, prioritize (incl. backlog), and deploy an integrated Data Group and/or Product roadmap, working in close collaboration with relevant stakeholders and DDIT partners, in alignment with the Capability and Platform strategy roadmaps.
- Stakeholder engagement: Represent the Data Group and/or Product in digital governance boards and leadership meetings across the organization. Support continuous expansion of knowledge and foster adoption of a digital mindset in Regulatory Affairs. Communicate effectively with stakeholders at all levels to facilitate understanding and support for new data and technology initiatives related to the Data Group and/or Product
- Collaboration and Partnerships: Is the go-to person for all process, configuration, decision
  making and outcome, impacting the data group and/or product, with involvement of relevant
  Business Process Owner(s), business SMEs and stakeholders
- Oversee vendor(s) at the data group and/or product level, in collaboration with IT and the External Partnerships Team; monitor and track SLAs/KPIs, assess vendor performance periodically, assist the Capability Lead to decide the overall vendor relationship. Oversee integration(s) with upstream and downstream data group(s) and/or product(s)
- Quality and Compliance: Take accountability to ensure adherence to Security and Compliance policies and procedures within the scope of the data group(s) and/or product(s).
- Project and Program support: Ensure support/resources for key projects and programs with impact to the data group(s) and/or product(s), ensuring timely delivery of high-quality milestones in alignment with business requirements
- Demand management: Raise demand(s) for data and/or technology services and operational support arising from various functions within RA

#### Minimum Requirements:

- 5+ years of relevant industry experience, strong understanding and direct relevant experience with the data and technology landscape of pharmaceutical regulatory affairs and Regulatory Information Management
- Proficient knowledge of EMA SPOR, FDA data standards, clinical data standards and/or other industry data standards.
- Experience with Master and Reference Data Management, RIM systems and configuration possibilities, and very knowledgeable in systems 'data model and standards.
- Proficient in using Controlled Vocabularies from different sources and with mapping to internal code lists. Strong negotiation skills, excellent verbal and written communications
- Experience in quality assurance/compliance, computer system validation within the

pharmaceutical/biotech/IT arena

- Experience with managing/owning Data and Technology Products
- Proficiency in data analysis and visualization tools (e.g., SQL, Python, R, Power BI) and Ticketing tools like ServiceNow. Strong understanding of statistical concepts and data modeling techniques
- Bachelor's degree or master's; Advanced degree in life science, pharmaceutical, technology or data science preferred.

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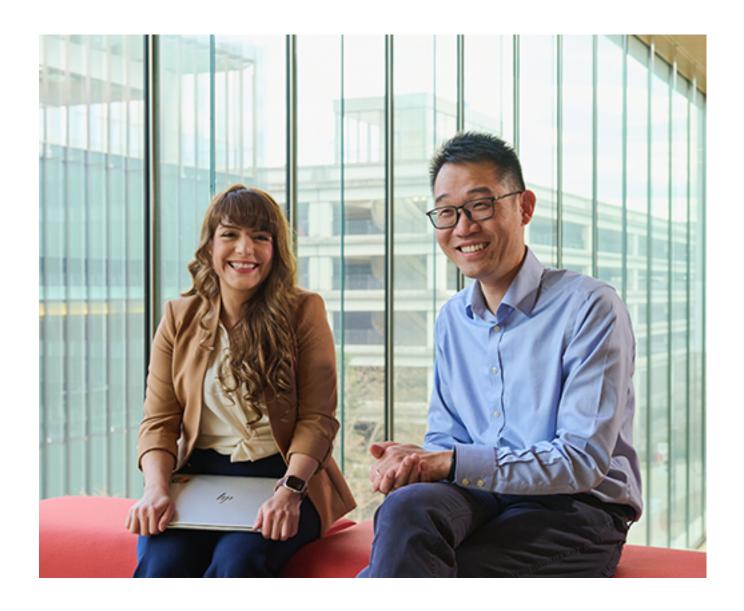
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