U NOVARTIS

Business Administration Capability Lead, RA Platform Operations

Job ID REQ-10050511 Apr 29, 2025 India

Summary

As a member of the RA Platform Operations team, the Business Administration Capability Lead will play a pivotal role in enhancing the organization's operational efficiency and technological advancement. This position is crucial for the Product & Data governance aspects, across RA Data & Technology Platforms.

The Business Administration Capability Lead is responsible for ensuring that all Technology Products are supported seamlessly from a Governance, User Account Management, and Content/Data security point of view, thereby minimizing disruptions to business operations. This role directly impacts the organization's ability to meet business needs and technical standards, ensuring the continuity and reliability of the Regulatory Affairs Technology infrastructure

About the Role

Major accountabilities:

Team Leadership:

- Lead a team to ensure alignment with organizational goals and business priorities related to Business Administration activities (i.e. Governance, User Account Management, and Content/Data security), and support the strategic vision for Platform Operations from a Capability level; foster a culture of excellence and continuous improvement
- Act as a Change Lead and implement change management strategies to ensure smooth adoption of technology initiatives, at the Capability level

Stakeholder Engagement:

- 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
- · Communicate effectively to ensure understanding and support for new technology initiatives
- Support continuous expansion of knowledge and foster the adoption of a digital mindset within Regulatory Affairs

Collaboration and Partnerships:

- Build and maintain collaborative and productive partnerships within the Capability and the Platform, and with relevant stakeholders to achieve business priorities.
- Oversee vendors at the capability level, across product(s), in collaboration with IT and the External

Partnerships Teams

Quality and Compliance:

- Ensure on-time, compliant, quality delivery of Business Administration activities for the assigned Capability/Product(s), aligned with the NVS Quality Manual
- Ensure adherence to Security and Compliance policies and procedures within the scope of the Capability and prepare for audit readiness and inspection requirements (incl. Related mitigations or actions triggered by audits & inspections).

Business Administration activities:

- Develop and manage resource plans for Business Administration activities, ensuring efficient allocation of resources to support business priorities
- Ensure access control, security management, and continuous operation and availability of technology products.
- Act as the first-level support for business administration issues and ensure a harmonized approach across all technology products.
- Collaborate closely with IT to ensure optimal systems performance and availability, assisting in the identification and troubleshooting of any issues that may arise
- Ensure Business Administration Capability is fit for purpose (incl. related processes such as SOPs, WIs, Best Practices, etc.) and achieves the desired business value and impact
- Develop and implement business administration strategies and frameworks/standards to ensure compliance for the management of technology operations, focusing on efficiency and effectiveness including but not limited to: Governance Framework, Compliance & Regulatory Documentation, Risk Management Plan, User Account Management Procedures, Access Control Policies, Audit and Review Reports, Data Security Plan, etc. – as needed/relevant

Project and Program Support:

 Provide support/resources for key projects and programs impacting the Capability and/or underlying Service(s)/Product(s), ensuring timely delivery of high-quality milestones in alignment with business requirements

Demand Management:

- Effectively manage demand(s) for technology services and operational support related to business administration activities, arising from various functions withing Regulatory Affairs
- Monitor service delivery performance and backlog

Industry Trends:

Stay updated with industry trends and emerging practices to drive agility, innovation, speed, efficiency, effectiveness, and continuous improvement within the Capability

Key performance indicators:

Achieve key Regulatory Affairs business objectives and stakeholder milestones by leading the Capability, ensuring timely and on budget delivery of the Capability roadmap Manage Business Administration activities supported by the Capability in a timely and successful manner (e.g. through the measure of number of security incidents, percentage of system uptime, time taken to resolve security issues, etc.) Improve user experience for solutions and services for product(s) underlying the capability Enable RA operational execution through

dedicated management of the Capability and underlying Products and Services, maximizing the value provided by our systems:

- Improvement of the landscape performance and user satisfaction
- Adoption and harmonization of high performing technology solutions leading to simplification of the landscape and reduction in number of systems, delivered on time and in budget
- No critical findings in audits and inspections related to the business administration processes for RA Products

Minimum Requirements:

Bachelor's degree, master's; Advanced degree in life science, pharmaceutical, technology, or data science preferred.

Work Experience and Skills:

- 8+ years of relevant industry experience
- Strong understanding and direct relevant experience with the Business Administration landscape of pharmaceutical regulatory affairs
- Advance knowledge of drug development process as well as international drug registration and approval, of Regulatory Business processes and information management
- Hands-on experience in technology process requirements
- Extensive experience leading meetings, driving change and cross-functional teams
- Excellent problem-solving skills and in seeking clarity in ambiguous situations
- Leadership in risk assessment, strategic thinking, prioritization, and global awareness
- Excellent business writing, communication and effective presentation skills
- Technically savvy
- Broad experience in quality assurance/compliance, computer system validation within the pharmaceutical/biotech arena, and strong knowledge of relevant regulatory requirements
- Strong experience in business administration activities (e.g. Governance, User Account Management, Content/Data security), in the support of technology products of medium & high complexity and criticality

Languages :

• Fluency in English as Business language

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

Division Development Business Unit Universal Hierarchy Node Location India Site Hyderabad (Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited Functional Area Research & Development Job Type Full time Employment Type Regular Shift Work No Apply to Job

Accessibility and accommodation

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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