

Sr. Business Analyst DDIT DEV RA

Job ID
REQ-10074325

3月 25, 2026

India

摘要

The primary objective of this position is to serve as a consultant and advisor, offering expert guidance to enhance complex business processes in KCM (Knowledge and Content Management) and Regulatory Labelling. We seek a seasoned professional with knowledge and expertise in the products and services developed globally to support the Regulatory Affairs function in Life Sciences Industry. This role brings in the expertise in Global Labelling processes along with knowledge of AI assisted content generation, structured content authoring and automated content translation to support the business SMEs in enhancing the current processes and implementing the right fit IT solutions for the enhanced processes.

About the Role

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The Business Analyst has a key role in describing and translating business requirements in a way that they are clear, complete and easily understood by the business and other relevant stakeholders. The Business Analyst is responsible for driving the discussions with product vendors for vendor selection, fit gap assessment along with refining the business requirements and functional specifications to meet the business objectives. The Business Analyst is also actively involved in supporting our in-house Innovation teams in developing custom in-house solutions as well as evaluating market offerings for various business requirements. Good technical background in conjunction with proven business analysis techniques and well-developed interpersonal skills are key success factors in this role.

Your responsibilities include but are not limited to

- Develop project rationale and perform scoping assessments to determine feasibility of projects
- Highlight/identify gaps in existing functionality and review requirements with stakeholders
- Research and assessment of leading products and offerings from various solution providers in the areas of Knowledge Management, Structured Content Management, translation and Labelling Solutions.
- Analyze the regulations coming up in the Regulatory Affairs area in collaboration with the business SMES to determine the impact on existing business processes and IT system configurations
- Develop a comprehensive requirement specification (URS, FS, CS, FRA) that will determine the estimate of cost, time and resources to implement new solutions for ensuring regulatory compliance.
- Support RFP process for vendor selection and Liaise between product vendor and business stakeholders to finalize the functional scope, understand “as-is” and define “to-be” processes
- Support in the development of project estimates and complete financial models (costs, savings, revenue opportunities, investment horizon, etc.)
- Ensure that relevant stakeholders are involved in specification of new services and/or major upgrades to existing services
- Ensure consistency and traceability between user requirements, functional specifications and testing & validation. Support validation and testing (OQ, PQ, UAT...) and Ensure implemented solutions are according to specifications and fit for purpose.

What you ' ll bring to the role:

- Support super user training and Keep abreast of internal IT systems and documentation requirements, standards (including quality management and IT security)
- Keep abreast of industry with the best practices in leveraging technologies for the business and with regulatory environments / requirements if applicable.
- Take accountability to ensure adherence with Security and Compliance policies and procedures within Service Delivery scope
- Work closely with business functions to identify AI opportunities, build business cases, and ensure AI investments deliver measurable business value.
- Manage Change Requests for labeling systems, ensuring all updates comply with 21 CFR Part 11 and GxP
- Expert understanding of business process analysis & design and system architecture concepts
- Good negotiation and facilitation skills. Ability to collaborate with a cross functional team on solution design
- Proven experience analyzing business needs, eliciting and documenting effective user requirements for GxP system. Knowledge of business process modelling and optimization.
- Excellent verbal and written communication skills in English and experience working with global teams

Desirable Requirements:

- Bachelor ' s degree in computer science, Computer Engineering or related technical discipline or equivalent experience demonstrated
- Hands on of 8 years ' experience in SDLC, system validation and Business Analyst role and with min of 5 years in Drug Development domain
- Experience in Regulatory IT systems implementation and hands-on experience on GenAI based solutions for document generation, management. Implementation experience of products in the Regulatory affairs area like, Veeva Vault, Documentum, Yseop etc.
- Life sciences regulatory domain knowledge and Proficiency with tools such as Jira, Confluence, Business process modelling tools
- Knowledge of the hierarchy between CCDS, CCSI (Company Core Safety Information), and local prescribing information. Knowledge of FDA (US), EMA (Europe) requirements.
- Experience in Managing GxP Projects and Related Fields is a plus Ability to manage medium size teams as part of project execution

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity, and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

部门

Operations

Business Unit

Information Technology

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Technology Transformation

Job Type

Full time

Employment Type

Regular

Shift Work

No

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