Sr. Spec. DDIT ISC QNova (Quality management Novartis)

Job ID
REQ-10001043
Juni 25, 2024
Indien

Zusammenfassung

The purpose of the role is to deliver Quality management services to the NBS IT division and its Customers to ensure that information assets are adequately protected and compliant. The Project Quality Manager will ensure alignment and consistency across the IT, business, service provider and other partners on quality and compliance for the IT projects.

About the Role

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Location : Hyderabad

- Perform validation impact analysis and risk assessments, both high level and functional, to ensure requirements coverage. Author key validation work, provide GxP related validation expertise and partner with key business collaborators (i.e. Manufacturing, Quality, Validation, Risk and Compliance, etc.) in defining the CSV strategy.
- Should be thorough with Document Management processes i.e. create, review, update and approve CSV work including Validation Assessment, Validation Plan, Test Plan, Qualification scripts (IQ, OQ, PQ), Test protocols and reports, Traceability Matrix and Validation Summary Report.
- Experience of SDLC (Waterfall or Agile methodologies or DevOPS) and responsible for tracking, monitoring and controlling validation process to ensure timely and cost-effective delivery of the system to the business users.
- Ensure implementation and monitoring of IT compliance, records management and information risk management during IT projects, to ensure the integrity, confidentiality and availability of information owned, controlled or processed by the organization
- Evaluates the risks arising from control deficiencies, gaps and facilitates risk mitigation planning. Supports Audits, Inspections and Assessments performed by internal and external agencies.
- Ensure adequate analysis have been performed for relevant testing conditions based on functional risk assessment, test overview list, test plan, test results, test deviations and change requests.
- Identify and log issues found during validation execution, perform root-cause analysis to define corrective and preventive measures to be taken and work closely with relevant product teams to prioritize and track validation incidents to closure.

- Good hands - on experience in Development and Automation of Integration Solutions like EDI, API Management , Data Virtualization and (MFT) Managed File Transfer using products like IBM SI, AxwayB2Bi, APIGW and MFT and TIBCO's Data Virtualization
- Development experience in any Cloud technology AWS, Azure or GCP. EDI Integrations design and development and providing Technical Support to the team.
- Good hands - on technical experience in managing platforms preferably on Linux OS and expertise in DevSecOps tool stack (Jenkins, Artifactory, Ansible)

Key requirements :

- Bachelor’s degree in Engineering/ Sciences or relevant technical experience with 8+ years of working experience in IT Quality management / Information Security and Risk management / service delivery positions in regulated environment / pharma / life sciences.
- Knowledge on Waterfall, Agile and DevOps methodology.
- Experience working within the guidelines provided by regulatory agencies such as FDA, MHRA, etc. on one or more of the following areas: CFR Title 21 (parts 11, 210, and 211), Annex 11, GAMP, V-Model, CAPA, GxP (GMP, GLP, GCP, GVP, etc.), ERES regulations and Computer Systems Validation (CSV) coupled with ability to apply the same.
- Familiar with compliance requirements (e.g. SOX, FDA/GxP, GQO, COBIT, Records Management, Privacy, Legal, BCM/Disaster Recovery).
- Working knowledge of Risk Management, Audit management and periodic or control maturity assessment with adequate understanding on Change Management and Change Control Procedures, Deviation Handling, and CAPA management.
- Risk management background with experience in risk management related roles.
- Knowledge of various Requirement management and Test management tools (like HPALM, Jira, Confluence, etc.) and templates used throughout the Pharmaceutical industry.

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You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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