Spec. DDIT ISC QNova

Job ID
REQ-10015193
Jul 17, 2024
India

Summary

-Supports the implementation of the information security, governance and strategy per the information management framework through business partnering.

About the Role

Job Title - Sr. Spec. DDIT ISC QNova (Quality management Novartis)

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 5+ 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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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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.

Division

Operations
Business Unit
CTS
Location
India
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com 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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