IT Project Quality Sr. Spec. DDIT ISC QNova

Job ID
REQ-10056974

7月 08, 2025

Mexico

摘要

A proven compliance expert with strong people and service management skills. The Project Quality Manager will ensure alignment and adherence across the IT, business, service provider and other stakeholders on quality and compliance for the IT projects.
Deliver Quality and compliance management services to the DDIT division and its Customers to ensure that information assets are adequately protected and compliant.

About the Role

MAJOR ACCOUNTABILITIES

- Perform validation impact analysis and risk assessments, both high level and functional, to ensure requirements coverage.
- Author key validation deliverables, provide GxP related validation expertise and partner with

key business stakeholders (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 deliverables 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.
- Provides compliance & risk management guidance for IT projects, including the evaluation, implementation and monitoring of information security controls.
- 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.

- Interface with business and IT partners to ensure Novartis practices are aligned with regulatory expectations and industry best practices.

- Supports Audits, Inspections and Assessments performed by internal and external agencies.
- Evaluates the risks arising from control deficiencies, gaps and facilitates risk mitigation planning
- First point of contact for all quality related queries on the projects, follow up resolution of identified quality exposures and escalation to line management if critical situations are not resolved in due course.
- 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.
- Train and coach the project team, as required, on relevant project procedures, good documentation practice, good testing practice and CSV basics, where applicable
- Manage appropriateness of preparation and readiness of the project for handover of the system/processes to the operational organization together with the project managers.
- 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.

KEY PERFORMANCE INDICATORS / MEASURES OF SUCCESS

- Information risk and compliance status proactively monitored and improved to ensure reduction of critical audit findings
- The Novartis Business Information Security and Risk Management (ISRM) standards are established and the maintenance processes are in place.
- Achieved quality solutions while meeting agreed targets for time, budget and customer satisfaction.

JOB DIMENSION

- Capable of Delivering quality solutions for projects and services having a Low to medium impact across the 6 change dimensions (process, organization, location, data, application,

technology).
- Capable to conduct Quality Reviews to evaluate if processes and deliverables fulfil the requirements for quality, to uncover errors or deficiencies in processes and deliverables, and to identify strengths and opportunities for improvement.

PROFESSIONAL COMPETENCIES / EXPERIENCE

- 10+ years of working experience in IT Quality management / Information Security and Risk management / service delivery positions in regulated environment / pharma / life sciences
- Bachelor's degree in Engineering/ Sciences or relevant technical experience.
- 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.
- Should have adequate understanding on Change Management and Change Control Procedures, Deviation Handling, and CAPA management.
- Experience with cloud-based applications, Documentum, enterprise applications and Infrastructure services is a plus.
- Certifications in the area of Information security (e.g. CISA, CISSP, CISM etc.) , Regulatory areas would be added advantage.
- Able to challenge status quo or traditional approach and propose a risk based approach keeping in mind both agility and quality.
- Risk management background with experience in risk management related roles.
- Able to engage with senior leaders in the company.
- 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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部门
Operations

Business Unit
CTS

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Technology Transformation

Job Type
Full time

Employment Type
Regular

Shift Work
No

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