

Sr. Spec. DDIT ISC QNova

Job ID REQ-10064182

10月 09, 2025

India

摘要

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

About the Role

Location: Hyderabad, India #LI-Hybrid (12 days/month in office)

Ensure effective and consistent implementation and operation of ISRM processes, methods, policies and tools in Function supporting all ISRM objectives and QA Computer Systems Validation for DDIT projects and systems operation

Deliver Quality management services to the NBS IT division and its Customers to ensure that information assets are adequately protected

MAJOR ACCOUNTABILITIES

- 1. Manages compliance of the system during its lifecycle, with regards to Regulatory and Novartis Internal Standards. This includes management of all system-related changes (approved documents, system changes from functional acceptance testing onwards). This is performed through document reviews & coordination of various activities including testing, performing Project Tollgates etc.
- 2. Provides compliance & risk management guidance for IT projects, including the evaluation and recommendation of technical controls. Drive continuous improvement of the quality system to meet and sustain compliance with internal and external regulatory requirements, including creation of SOPs as applicable
- 3. Ensure implementation and monitoring of information security, IT compliance, records management and information risk management program in the DDIT, to ensure the integrity, confidentiality and availability of information owned, controlled or processed by the organization
- 4. 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.
- 5. Follow up resolution of identified quality exposures and escalation to line management if critical situations are not resolved in due course.
- 6. Drive shifting of emphasis from "final inspections" to "in-process reviews and controls". Contribute to business decisions in the definition and assessment of IT requirements.
- 7. Support the development and delivery of training in quality matters. Interface with business and IT partners to ensure Novartis practices are aligned with regulatory expectations and industry best practices.
- 8. Supports Audits, Inspections and Assessments performed by internal and external agencies. Evaluates the risks arising from control deficiencies, gaps and facilitates risk mitigation planning

Essential Requirements:

- Good understanding and knowledge of business processes in a global health care industry
- Good knowledge of Project and Quality Management methodologies, (e.g. ICE, SDLC), Quality Systems and Policies
- 12+ years of working experience in IT Quality management / project management / service delivery positions in regulated environment / pharma / life sciences
- Experience working in GxP, CSV Computerized system validation and 21 CFR Part 11 requirements
- Risk management background with experience in risk management related roles. Knowledge of

General IT Software Engineering Life Cycle, project management and compliance domains.

- Experience working in diverse cultural environment and in a matrix organization
- · Implementation of new processes or methodologies
- Good understanding of business processes and objectives
- · Good written and verbal communication and presentation skills
- High level of customer focus with proven problem solving skills
- Familiar with compliance requirements (eg. SOX, FDA/GxP, GQO, COBIT, Records Management, Privacy, Legal, BCM/Disaster Recovery)

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部门 Operations
Business Unit Universal Hierarchy Node
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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