NOVARTIS

Sr Specialist DDIT ISC QNova (Computer System Validation)

Job ID
REQ-10029535
Nov 18, 2024
Czech Republic

About the Role

Key Responsibilities:

- Execute risk and compliance processes and oversight, operational tasks.
- 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.
- Own Document Management processes and 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.
- 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.
- Evaluate the risks arising from control deficiencies, gaps and facilitates risk mitigation planning; support Audits, Inspections and Assessments performed by internal and external agencies.
- Manage appropriateness of preparation and readiness of the project for handover of the system/processes to the operational organization together with the project managers.
- Act as 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.
- 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.
- Performs EDI Integrations design and development and providing Technical Support to the team.

What you will bring to the role:

- Bachelor’s degree in Engineering/Sciences or relevant technical experience
- 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.
- Strong 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
- Strong hands on technical experience in managing platforms preferably on Linux OS and expertise in DevSecOps tool stack (Jenkins, Artifactory, Ansible)
- Excellent communication and senior stakeholder management skills, with experience working cross-functionally and transnationally.

Desirable requirements

- Audits Compliance, Communication, Compliance Assessments, Compliance Training, Influencing Skills, Quality Assurance (QA), Regulatory Compliance Management.

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

You'll receive (CZ only):
Monthly pension contribution matching your individual contribution up to 3% of your gross monthly base salary; Risk Life Insurance (full cost covered by Novartis); 5-week holiday per year; (1 week above the Labour Law requirement) ; 4 paid sick days within one calendar year in case of absence due to sickness without a medical sickness report; Cafeteria employee benefit program – choice of benefits from Benefit Plus Cafeteria in the amount of 12,500 CZK per year; Meal vouchers in amount of 105 CZK for each working day (full tax covered by company); Public transportation Allowance; MultiSport Card. Find out more about Novartis Business Services: https://www.novartis.cz/

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

Accessibility and accommodation:
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Role Requirements

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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CTS
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Site
Prague
Company / Legal Entity
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Technology Transformation
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Employment Type
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