NOVARTIS

Sr. Specialist Qualification Engineer

Job ID
REQ-10021211
Sep 11, 2024
Mexico

Summary

-Contribute to challenge and improve local/simple business processes, products, services, and software through data analysis. -Engage with business representatives and support the appropriate DDIT teams and Functions to develop business requirements and deliver data driven recommendations to improve efficiency and add value.

About the Role

Major accountabilities:

- Participate in projects and operational changes to ensure that the creation of the qualification documentation is in compliance with Novartis standards and procedures
- Create / Update the CSV deliverables for OT systems as per Novartis procedures
- Advise and direct the site teams on industry best practices for the development of CSV protocols (including risk assessments, user requirements, functional specifications, and test qualifications)
- Engage with the In-house service of qualification engineers / technical writers, to ensure consistency of documentation and compliance
- Provide test management for the execution of qualification activities
- Provide expertise and best practice on the use of the electronic validation and lifecycle management tool for commissioning / qualification activities
- Participate in CSV related investigations and issue resolution, ensuring effective and timely remediation
- Collaborate with Quality Assurance and e-Compliance teams to ensure that CSV activities are in compliance with Novartis procedures.
- Act as a data quality checker of the Master Equipment Inventory of all sites

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Key performance indicators:

- Feedback on dedicated phases for Project execution (quality, time) -Degree of customization vs configuration of COTS solutions.
- Process efficiency (specific scope) -Steady/Uninterrupted process flow (specific scope) -Completeness and accuracy of Business Process Model (BPM) -local or non-complex processes -Business process documentation up to date (specific scope)

Minimum Requirements:
Work Experience:

- Bachelor's degree in Computer Science, Engineering, or a related field. Master's degree preferred.
- Minimum of 10 years of experience in computer system validation, with a focus on process automation systems.
- In-depth knowledge of regulatory requirements (e.g., FDA, GxP, 21 CFR Part 11) and industry best practices related to CSV.
- Strong understanding of software development lifecycle methodologies and their application to CSV activities.
- Excellent problem-solving and analytical skills, with the ability to identify and resolve complex CSV issues.
- Strong communication and interpersonal skills, with the ability to effectively collaborate with cross-functional teams and stakeholders at all levels of the organization.
- Detail-oriented mindset, with a focus on accuracy and compliance.
- Ability to work independently, prioritize tasks, and meet deadlines in a fast-paced environment.
- Certifications in CSV or related fields (e.g., GAMP 5, RAPS) are a plus.

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

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Operations
Business Unit
CTS
Location
Mexico
Site
INSURGENTES
Company / Legal Entity
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Employment Type
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