

## Sr. Specialist Qualification Engineer

Job ID  
REQ-10021211

9月 11, 2024

Mexico

### 摘要

-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

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.

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部门

Operations

Business Unit

CTS

地点

Mexico

站点

INSURGENTES

Company / Legal Entity

MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.

Functional Area

Technology Transformation

Job Type

Full time

Employment Type

Regular

Shift Work

No

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