Senior Specialist, Qualification Engineer

Job ID
REQ-10012373
Juli 10, 2024
Tschechische Republik

Zusammenfassung

About the department: At Novartis, our mission is to transform lives through radioligand therapies (RLT) with nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

About the Role

We are seeking a highly skilled and experienced individual to join our team as a Qualification Engineer. In this role, you will be responsible to qualify the Operational Technology (OT) systems and be the lead engineer that is responsible for specific types of operational technology, within the RLT ITOT function. You will collaborate with various partners to ensure compliance with regulatory requirements and industry best practices. You will provide guidance and expertise to multi-functional teams, ensuring that CSV activities are effectively driven throughout the OT systems lifecycle.

Role Responsibilities:

- 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). Point of Contact for improvement projects related to the enhanced compliance of OT related procedures and practices.
- 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 standard process 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
- Perform and collate output of audit trail risk assessments to ensure consistency across sites and for engagement with suppliers for potential software upgrades
- Participate in the system lifecycle management process, to ensure identified system flaws are investigated and remediated to meet the compliance requirements
- Provide training and guidance to team members and collaborators on CSV principles, requirements and standard methodologies.

What you'll bring to the role:

- Bachelor's degree or equivalent experience in Computer Science, Engineering, or a related field. Master's degree preferred.
- 5+ years of demonstrated ability 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 standard processes 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 multi-functional teams and collaborators at all levels of the organization.
- Meticulous approach, 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.

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.

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

You’ll receive: Read our handbook to learn about all the ways we’ll help you thrive personally and

professionally: Novartis Life Handbook

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

Restrictions on working flexibility may apply to this position and can be discussed at interview as required

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 inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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Corporate
Ort
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Employment Type
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Shift Work
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