NOVARTIS

Equipment Qualification Engineer

Job ID
REQ-10015314
Jul 18, 2024
USA

Summary

Posting Title: Equipment Qualification Engineer Onsite in East Hanover, NJ About the role: Manage commissioning and qualification (C&Q) activities for laboratory equipment, instrumentation and computerized systems compliant with corporate, local, and regulatory procedures and expectations. Responsible for handling the C&Q activities for multiple projects simultaneously to meet established deadlines. This role is responsible for scheduling and executing equipment qualification and CSV activities end to end, to include all required qualification documentation. The Equipment Qualification Engineer will assist in the investigation of Out of Specification (OOS), Out of Expectations (OOE), and product deviations related to systems, equipment, and laboratory instruments in area of responsibility. Your Key Responsibilities: Develops a tailored approach for each project, including, assessing vendor validation packages, performing gap analysis to User Requirement Specifications (URS), developing plans and protocols using a risk-based approach that comply with FDA and company policies and procedures. • Develops Commissioning and Qualification policies and procedures to enhance the company's ability to conform to and maintain compliance with site, corporate and regulatory standards. • Manages third-party contracts and contractors to perform C&Q tasks as required. • Authors and/or manages authoring of commissioning, qualification, and validation plans, validation protocols, validation summary reports, system impact assessments, and traceability matrices. • Liaise with end user groups to ensure correct specification of equipment and systems. • Performs system and equipment qualification using a risk-based approach (FMEA, PHA, etc.). • Performs risk assessments to confirm safe and compliant designs, recommends additional controls as needed and ensures that all activities are following cGMPs, Health Authority regulations and Novartis Policies and Procedures. • Reviews project documentation (URS, FRS, Technical Specifications, Functional Specifications) • Partners with Quality Assurance to ensure a quality and compliant manufacturing environment and executes projects in alignment with key local and global stakeholders and according to life cycle costs and project schedules

About the Role

Role Requirements:

- Bachelor's degree in engineering or equivalent experience is required; Master's Degree in Engineering is preferred.
- 4+ years engineering experience in pharmaceutical or related industry is required
- Highly knowledgeable in cGMP and regulatory requirements, including CSV requirements and 21 CFR Part 11 compliance.
- Strong technical writing skills
- Supervisory or management of projects and contract personnel.

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

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

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $97,600- $146,400/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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EEO Statement:

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Business Unit
Innovative Medicines
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USA
Site
East Hanover
Company / Legal Entity
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Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job
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