

Equipment Qualification Engineer

Job ID
REQ-10015314
Juli 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.

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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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Global Drug Development

Business Unit

Innovative Medicines

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New Jersey

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East Hanover

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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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