Senior Validation Engineer / Lead

Job ID
REQ-10066844

11月 16, 2025

USA

摘要

The Senior Validation Engineer is a subject matter expert in the Commissioning and Qualification program and provides leadership and mentorship in the qualification of equipment, utilities, and processes.

About the Role

Location: Durham, NC

Please note this role is on-site 5 days a week and does not have the ability to work remotely. This role is based in Durham, NC.

Novartis is unable to offer relocation support for this role: *please only apply if this location is accessible for you.*

Responsibilities:

- Develops a tailored approach for each project they are assigned including assessing vendor validation packages, performing gap analysis to User Requirements, developing plans and protocols using a risk-based approach that comply with company policies and procedures, and completing trace matrices.
- Reports on progress and roadblocks to the project team(s).
- 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.
- Development, execution, and management of small to medium size projects.
- Manages CQV contractors to perform tasks as required.
- Authors and/or manages authoring of commissioning, qualification and validation plans, validation protocols, validation summary reports and requirement trace matrices.
- Validation using risk-based approach (FMEA, PHA, etc.). Performs risk assessments to confirm safe and compliant designs and recommend additional controls.
- Reviews project documentation (URS, FRS, Technical Specifications, Functional Specifications).
- Participates in discussions with internal business partners on priorities, timelines and transparent sharing of information.
- Partners with Quality to ensure a quality and compliant manufacturing environment.
- Manages workload to ensure timely approval of validation testing and documentation.
- Supports the validation department during inspections or audits as a Subject Matter Expert.
- Other related duties as assigned

Requirements:

- BS/MS degree in Chemical, Industrial, Mechanical, or other related engineering/science discipline with 7 years of relevant engineering experience supporting GMP operations.
- 7 years of experience in the engineering design and support or qualification of commercial grade pharmaceutical or biotechnology process equipment and utilities.
- Ability to read/interpret engineering drawings and design documents.
- Excellent technical writing and verbal communication skills.
- People oriented and a team player
- Proficient in Microsoft Word, Excel, PowerPoint, and Project.
- In-depth knowledge of FDA and EMEA regulations particularly 21 CFR part 11, 210, 211, Annex 1.
- Working knowledge of ICH Q8, Q9, Q10 and other international regulatory requirements.
- Familiarity with the following equipment: bioreactors, centrifuges, laboratory systems, TFF systems, chromatography skids, fillers, autoclaves, parts washers.
- Experience managing 3rd parties (both in-sourcing and outsourcing).
- Ability to prepare contingency plans and logically work through complex issues in a high-pressure situation.

Skills:

- Automation.
- Business Continuity.
- Change Control.
- General Hse Knowledge.
- Including Gdp.
- Knowledge Of Capa.
- Knowledge Of Gmp.
- Managing Performance Improvement.
- Manufacturing (Production).
- Project Commissioning.
- Project Engineering.
- Project Execution.
- Risk Management.
- Root Cause Analysis (Rca).

Languages:

- English

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $103,600 and $192,400/year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards. US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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.

部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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