

Validation Engineer II

Job ID
REQ-10065344

10月 30, 2025

USA

摘要

The Validation Engineer II, assists with the authoring, executing and reviewing of SOP's, commissioning documentation, documents required for validation/qualification.

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:

- Supports the development of Validation/Qualification documents including drafting risk assessments, qualification protocols, deviations, and reports. Supports the execution of validation/qualification activities for the site (including manufacturing equipment, QC lab equipment, utilities).
- Reviews, evaluates and analyzes validation data for accuracy and adequacy.
- Supports the validation execution strategy and timeline for sustained commercial and clinical operations within a validation GMP environment.
- Assists with change management validation impact assessments.
- Supports the site validation periodic re-evaluation program including periodic reviews and requalification's.
- Assists with Validation lifecycle documents.
- Manages workload to ensure timely approval of validation testing and documentation.
- Supports the validation department during inspections or audits.
- Other related duties as assigned.

Requirements:

- BS/MS degree in Chemical, Industrial, Mechanical, or other related engineering/science discipline with a minimum of 2 years of relevant engineering experience in the pharmaceutical or Biopharmaceutical industry.
- Familiarity with good engineering practices, validation tools and processes, risk management, GAMP 5 applications and practices (including environmental mapping and use of Thermal Mapping equipment is preferred).
- Experience in cGMP environment (IQ, OQ, PQ).

- Familiar with current industry best practices, including ASTM e2500 to plan efficient/risk-based validation projects.
- Strong technical writing and verbal communication skills.
- Proficient in Microsoft Word, Excel, PowerPoint, and Project.

Languages:

- English.

Novartis Compensation and Benefit Summary

The pay range for this position at commencement of employment is expected to be between \$70,000 and \$130,000/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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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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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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

Universal Hierarchy Node

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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