Validation Engineer III

Job ID
REQ-10066846

11月 21, 2025

USA

摘要

The Validation Engineer III, is responsible for authoring, executing and reviewing/approval 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:

- Oversees URS, protocols, reports & support records to ensure compliance, timely resolution of documentation, compliance, and quality system issues. Identify, coordinate, execute and provide oversight of validation activities related to the start-up, commissioning, qualification, validation of a cGMP manufacturing facility (including manufacturing equipment, QC lab equipment, utilities).
- Performs environmental mapping and other miscellaneous validation activities.
- Evaluates and analyzes validation data for accuracy and adequacy.
- Supports the development of validation execution strategy and timeline for sustained operation within validated GMP environment.
- Collaboratively conducts Risk Assessments and Impact assessments and establish system boundaries.
- Owns validation Lifecycle documents including Validation Plans, Impact Assessments, and Validation Reports.
- Reviews and supports Computer Systems Validation efforts for global systems.
- Manages workload to ensure timely approval of validation testing and documentation.
- Assists Quality Assurance, Production, Quality Control and other departments during inspections or audits.
- Additional duties may include attendance at client meetings, preparation of project budgets, review of invoices, and any other duties as required to control financial and execution related aspects of project.
- Other related duties as assigned.

Requirements:

- BS/MS degree in Chemical, Industrial, Mechanical, or related engineering discipline; or Science with 5 years of relevant experience in the pharmaceutical or Biopharmaceutical industry (validation or engineering experience preferred)..
- Experience with Biosafety cabinet smoke studies.
- Knowledge of Industry guidelines (ISPE, PDA), US and international regulations (FDA, ICH, ISO, EU) for validation of GMP facilities.
- Experience supporting FDA approved, commercial products.
- Experience in cGMP environment (IQ, OQ, PQ) is essential.
- Familiar with current industry best practices, including ASTM e2500 to plan efficient/risk-based validation projects.
- Experience with validation tools and processes, including environmental mapping and use of Kaye Validator.
- Familiar with GAMP 5 applications and practices.
- Excellent technical writing and verbal communication skills.
- Proficient in Microsoft Word, Excel, PowerPoint, and Project.
- Experience providing technical support for problems of moderate scope where analysis requires a review of a variety of factors and able to drive toward issue resolution.

Skills:

- Business Continuity.

- Change Control.
- Flexibility.
- General Hse Knowledge.
- Hvac (Heating Ventilation And Air Conditioning).
- Including Gdp.
- Installations (Computer Programs).
- Knowledge Of Capa.
- Knowledge Of Gmp.
- 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 $89,600 and $166,400/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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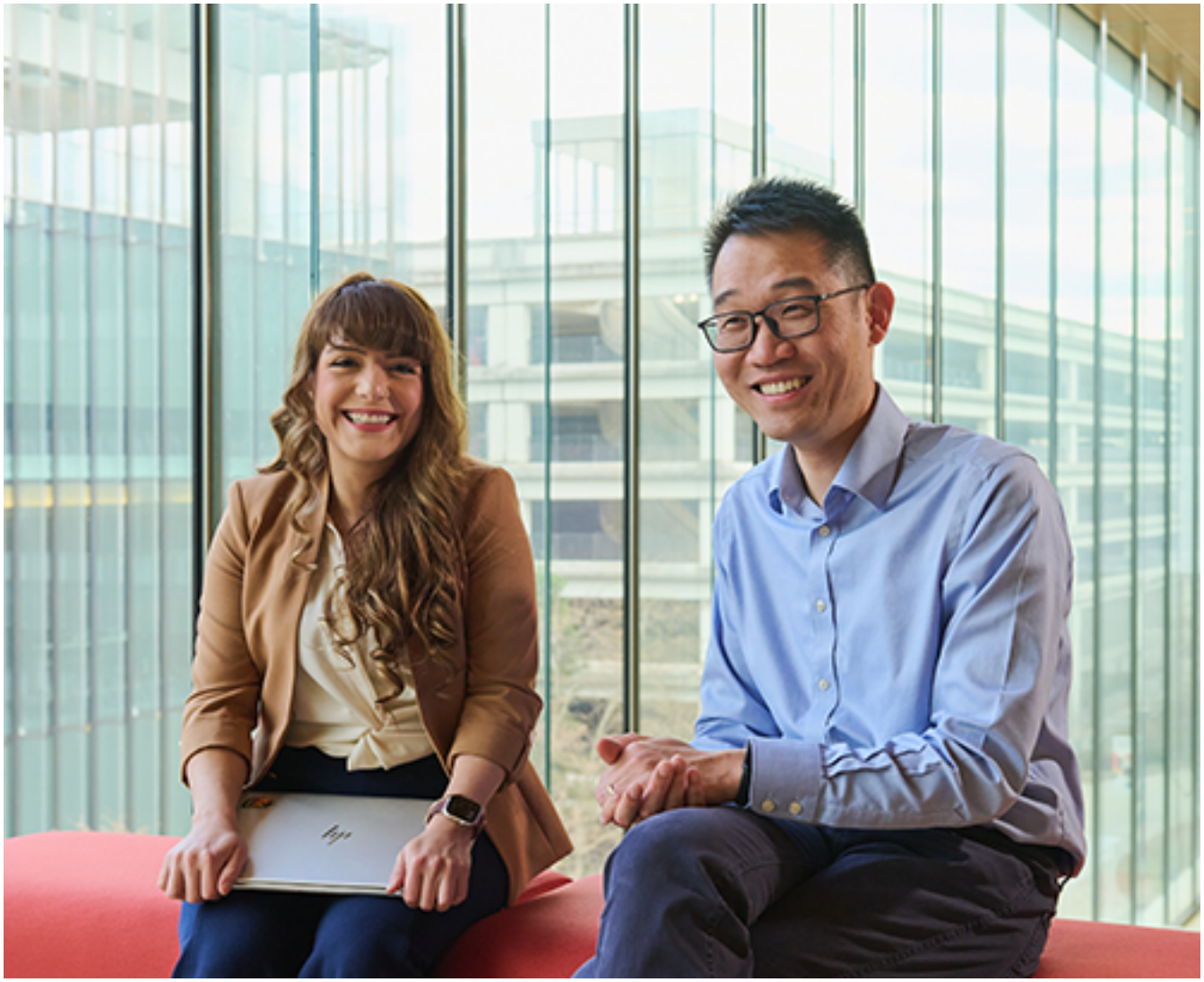

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