

Validation Lead

Job ID

REQ-10081690

Jul 05, 2026

LOC_US

About the Role

Key Responsibilities

- Lead the site validation strategy across process, cleaning, packaging, and ongoing process and cleaning verification activities.
- Own and maintain the Validation Master Plan, ensuring timely execution and inspection readiness.
- Establish, monitor, and improve validation performance metrics to support compliance and operational excellence.
- Provide technical leadership for validation risk assessments, investigations, and complex validation challenges.
- Partner with Engineering, Quality, Analytical Science & Technology, and IT to define the interfaces to equipment qualification / utilities qualification, system qualification, analytical method validation.
- Support product launches and technical transfers by defining robust validation approaches and delivering required data.
- Represent the site during audits, inspections, and validation governance activities while maintaining compliance standards.

Essential Requirements

- Bachelor's degree in Chemistry, Pharmacy, Chemical Engineering, Pharmaceutical Technology, or a related scientific discipline.
- 8 years of experience in manufacturing / manufacturing science and technology / technical development / quality in oral solid dosage pharmaceutical manufacturing.
- 5 years of experience executing process validation, including experience leading and managing validation projects.
- Proven expertise leading process validation, cleaning validation, and ongoing process verification programs.
- Strong knowledge of quality systems applied statistics, and global regulatory requirements.
- Demonstrated success managing complex cross-functional projects and authoring technical validation documentation.

Desirable Requirements

- PhD Chemistry, Pharmacy, Chemical Engineering, Pharmaceutical Technology, or equivalent.

The salary for this position is expected to range between \$126,000 and \$234,000 per 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.

To learn more about the culture, rewards and benefits we offer our people click [here](#).

#LI-Onsite

Role Requirements

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: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Division

DIV_TO

Business Unit

Production / Manufacturing

Location

LOC_US

Site

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Gene Therapies

Functional Area

FCT_TO

Job Type

Full time

Employment Type

Regular

Shift Work

No

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