

Engineer III, Analytical Instrumentation

Job ID REQ-10067310

11月 25, 2025

USA

摘要

#LI-Onsite

Location: This role is based in Durham, NC. Novartis is unable to offer relocation support: please only apply if accessible.

Bring your expertise to a role where precision and innovation drive progress. As Engineer III, Analytical Instrumentation, you'll be the subject matter expert ensuring critical laboratory systems operate flawlessly across Quality Control and Technical Research. From leading instrument lifecycle management to solving complex technical challenges, you'll play a key role in maintaining compliance and supporting groundbreaking science. This is your chance to influence processes that enable life-changing therapies while fostering reliability and operational excellence.

About the Role

Key Responsibilities

- Serve as subject matter expert and system owner for assigned laboratory instrumentation, ensuring compliance and optimal performance.
- Oversee qualification and lifecycle management of new and existing instruments to maintain validated state and regulatory standards.
- Investigate instrumentation deviations thoroughly and implement robust corrective actions to prevent recurrence and improve reliability.
- Manage change control processes for qualified systems and laboratory modifications, ensuring documentation accuracy and compliance.
- Develop and implement equipment reliability strategies that are cost-effective, compliant, and aligned with operational excellence principles.
- Perform or supervise calibrations and maintenance activities on laboratory instruments to ensure accuracy and minimize downtime.
- Define and document equipment specifications through User Requirements (URS), Functional Specification (FS) and Detail Design Specifications (DDS) to support procurement and validation processes.
- Support internal and FDA audits by providing technical expertise and timely responses to observations related to instrumentation.
- Lead or provide SME support for laboratory projects and technology transfer initiatives, translating process needs into equipment requirements.

Essential Requirements

- Bachelor's degree in Chemical, Electrical, Mechanical Engineering, or related technical field.
- Minimum 5 years of experience in pharmaceutical or biopharmaceutical GMP operations (or 9 years in lieu of degree).
- Strong knowledge of FDA regulations, GMP systems, and compliance in highly regulated environments.
- Proven ability to troubleshoot complex technical issues and implement effective solutions.
- Excellent oral and written communication skills, including strong technical writing ability.
- Applied knowledge of Quality by Design and operational excellence tools to improve processes and outcomes.
- Ability to lift and move materials (up to 50 lbs.) safely.

Desirable Requirements

- Experience supporting laboratory instrumentation in gene therapy or biotechnology environments.
- Project Management certification (e.g., PMP) or advanced degree in a related engineering discipline.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$89,600 and \$166,400 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.

Company will not sponsor visas for this position.

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

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

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

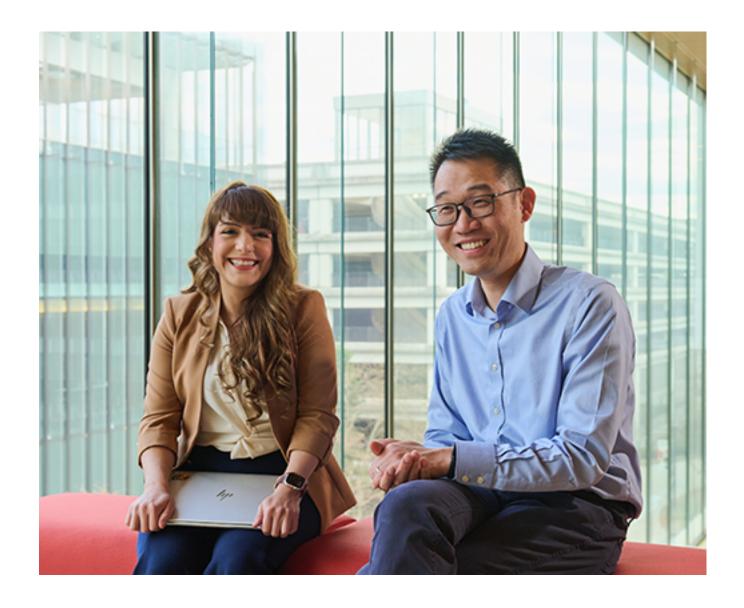
Functional Area Technical Operations

Job Type Full time

Employment Type Regular

Shift Work No

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