NOVARTIS

Quality Assurance Engineer

Job ID
REQ-10088164
сен 21, 2026
США

Сводка

Imagine being at the forefront of delivering life-changing therapies to patients who need them most. As a Quality Assurance Engineer, you will play a critical role in ensuring quality, compliance, and operational excellence across our GMP manufacturing environment. Working closely with Engineering, Manufacturing, Validation, and Technical Operations teams, you will help maintain a state of inspection readiness, drive quality improvements, and support the production of innovative gene therapy products. This is an opportunity to make a meaningful impact while collaborating with talented colleagues in a fast-paced, highly regulated environment where quality is at the center of everything we do.

About the Role

Location:

- This position will be located in Durham, NC and will be a hybrid role, where you must be onsite at least 3 days a week.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Provide QA support for clinical and commercial gene therapy manufacturing operations.
- Ensure compliance with GMP, FDA, and global regulatory requirements across manufacturing activities.
- Partner with Engineering, Validation, and Operations to maintain a compliant manufacturing environment.
- Support internal, customer, and regulatory audits and inspection readiness initiatives.
- Review and approve change controls, deviations, investigations, and CAPAs.
- Provide quality oversight for facility, utility, equipment, and process qualification activities.
- Collaborate with cross-functional teams to implement quality and compliance improvements.
- Review and approve project deliverables to ensure alignment with quality standards.
- Author, review, and approve SOPs and quality documentation supporting GMP operations.
- Work with suppliers and internal stakeholders to ensure ongoing quality and compliance standards.
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Essential Requirements:

- Bachelor’s degree in Engineering, Chemistry, Biochemistry, or a related scientific discipline.
- Minimum 5 years of experience in the biotechnology or pharmaceutical industry.
- Strong knowledge of current Good Manufacturing Practice regulations and quality systems.
- Experience supporting regulatory inspections and audits within a regulated manufacturing environment.
- Hands-on experience with commissioning, qualification, and validation activities.
- Experience managing deviations, corrective and preventive actions, and change control processes.
- Experience authoring, reviewing, or approving standard operating procedures and quality documentation.
- Strong communication, technical writing, problem-solving, and cross-functional collaboration skills.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $85,400 and $158,600 annually

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.

#LI-Hybrid

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)

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.

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Состояние
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Сайт
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Quality Assurance Engineer

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List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
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