

Quality Assurance Engineer

Job ID

REQ-10088164

Sep 21, 2026

LOC_US

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

Role Requirements

Division

DIV_TO

Business Unit

Quality

Location

LOC_US

Site

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Innovative Technologies Inc

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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