NOVARTIS

Manufacturing Quality Assurance Specialist

Job ID
REQ-10075033
апр 27, 2026
США

Сводка

Quality is not just a checkpoint here—it is the promise we make to patients. As a Manufacturing Quality Assurance Specialist at Novartis, you will be a hands-on partner to manufacturing teams, ensuring every stage of production meets the highest standards of quality, compliance, and scientific rigor. From shop floor presence to final product release, your expertise will directly influence patient safety and product integrity while helping drive continuous improvement in a fast-paced, purpose-driven manufacturing environment.

About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Shift:

- Shift schedule will be phased in as the site approaches go-live. We are planning for 12-hour rotating shifts which will include at least one weekend day.

Key Responsibilities:

- Provide proactive quality oversight through shop floor presence, walkthroughs, and real-time manufacturing support.
- Review and approve master and executed batch records to ensure compliant clinical and commercial production.
- Partner with manufacturing teams to ensure consistent, compliant processes aligned with GMP requirements.
- Support media, buffer, cell expansion, upstream, downstream, and aseptic filling manufacturing operations.
- Lead deviation and corrective action investigations, ensuring thorough root cause analysis and effective remediation.
- Review alarms, data integrity, and electronic records to confirm accuracy and regulatory compliance.
- Support internal and external audits, inspections, and regulatory readiness activities.
- Provide quality expertise in manufacturing batch record design, review, and continuous improvement.
- Analyze quality metrics, identify trends, and communicate actionable insights to management.
- Lead or contribute to continuous improvement and quality system enhancement projects.

Essential Requirements:

- Bachelor of Science degree in microbiology, chemistry, biochemistry, or a related scientific discipline.
- Minimum of five years of experience working in a regulated GMP manufacturing environment.
- Strong working knowledge and application of CFR, FDA, and EU regulatory requirements.
- Proven experience supporting or participating in FDA and EU regulatory inspections and audits.
- Hands-on experience reviewing, authoring, and approving quality procedures and standard operating documents.
- Demonstrated ability to manage deviations, investigations, and corrective and preventive actions to closure.
- Strong analytical skills with the ability to interpret data, identify trends, and recommend compliant paths forward.
- Excellent written and verbal communication skills with the ability to collaborate effectively across functions.

Desirable Requirements:

- Experience supporting viral gene therapies or orphan disease manufacturing programs.
- Experience leading or coordinating internal quality audits and inspection readiness activities.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $43.08 and $80.00 per hour.

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-Onsite

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.

Дивизион
Operations
Business Unit
Quality
Место
США
Состояние
North Carolina
Сайт
Durham
Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Job ID
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1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. mailto:us.reasonableaccommodations@novartis.com
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Durham/Manufacturing-Quality-Assurance-Specialist_REQ-10075033-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Durham/Manufacturing-Quality-Assurance-Specialist_REQ-10075033-1