NOVARTIS

QA Compliance Specialist

Job ID
REQ-10075906
апр 20, 2026
США

Сводка

In this role, you'll be at the heart of ensuring quality, compliance, and trust as we advance innovative gene therapies for patients worldwide. As a QA Compliance Specialist, your expertise will directly shape how quality systems are applied, strengthened, and continuously improved across the site—supporting both development and commercialization. You'll partner closely with cross-functional teams, influence critical decisions, and serve as a trusted voice on compliance, helping turn complex challenges into clear, risk-based solutions that protect patients and products alike.

About the Role

Location:

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

Key Responsibilities:

- Establish and maintain site quality system processes supporting development and commercialization of advanced gene therapy medicines
- Drive consistent execution of change control and non-conformance programs aligned with global quality system standards
- Lead investigations, root cause analysis, and timely corrective and preventive actions using a risk-based approach
- Serve as subject matter expert for change control, non-conformance, and quality documentation programs
- Lead non-conformance and change control review board meetings, ensuring effective governance and decision-making
- Review, approve, and author standard operating procedures to ensure regulatory and quality system compliance
- Analyze quality system metrics, trend performance, and present actionable insights to drive continuous improvement
- Provide guidance and training to site users on quality system processes and expectations
- Partner with manufacturing and operations on product investigations, deviations, and compliance activities
- Ensure adherence to Good Manufacturing Practice requirements and support inspection readiness across the site

Essential Requirements:

- Bachelor's degree in life sciences, chemistry, or related field, with significant experience in regulated manufacturing environments
- Proven experience in Quality Assurance within pharmaceutical, biotechnology, or gene therapy manufacturing
- Strong working knowledge of quality systems, including change control, non-conformance management, and deviation handling
- Demonstrated experience applying data integrity principles and ensuring compliance with current regulatory expectations
- Hands-on experience supporting Good Manufacturing Practice operations through quality management system execution
- Solid understanding of regulatory guidelines and expectations from global health authorities
- Experience reviewing, authoring, and approving standard operating procedures and quality documentation
- Ability to work independently, manage multiple priorities, and communicate clearly across technical and operational teams

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $81,200 and $150,800 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.

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
REQ-10075906

QA Compliance Specialist

Apply to Job

Job ID
REQ-10075906

QA Compliance Specialist

Apply to Job

Source URL: *https://novartis.ru/ru-ru/careers/career-search/job/details/req-10075906-qa-compliance-specialist*

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
3. mailto:us.reasonableaccommodations@novartis.com
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Durham/QA-Compliance-Specialist_REQ-10075906-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Durham/QA-Compliance-Specialist_REQ-10075906-1