NOVARTIS

QA Compliance Expert / Lead

Job ID
REQ-10075908
апр 20, 2026
США

Сводка

Step into a role where quality leadership directly shapes the future of gene therapies. As a QA Compliance Expert / Lead, you will be a trusted voice in ensuring that innovative medicines are developed and commercialized with the highest standards of quality, integrity, and compliance. Partnering closely with manufacturing, development, and global quality teams, you will lead critical quality system activities, mentor others, and drive meaningful improvements that safeguard patients and advance Novartis' mission to reimagine medicine.

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:

- Lead site quality system processes supporting development and commercialization of gene therapy medicines
- Serve as subject matter expert for change control, nonconformance, and documentation programs
- Drive consistent execution of investigations, root cause analysis, and corrective and preventive actions
- Review and approve change controls and nonconformances in alignment with quality system requirements
- Mentor and train quality assurance colleagues on quality system processes and best practices
- Partner with manufacturing and operations on product-related investigations and deviations
- Own, author, and maintain standard operating procedures to ensure regulatory compliance
- Monitor, analyze, and trend quality system metrics to identify improvement opportunities
- Lead site forums and review boards supporting quality alignment and decision-making
- Support internal and external inspections as a quality system expert, ensuring readiness and compliance

Essential Requirements:

- Bachelor's degree in a relevant scientific or technical discipline
- Minimum eight years of quality assurance experience, including at least five years in pharmaceutical environments
- Expert knowledge of quality systems, including change control and nonconformance management
- Proven experience reviewing quality systems data to identify compliance and data consistency issues
- Demonstrated expertise in data integrity principles and regulatory expectations
- Advanced understanding of United States Food and Drug Administration and European Medicines Agency regulations
- Hands-on experience authoring, reviewing, and owning standard operating procedures
- Strong written and verbal communication skills, including technical writing proficiency

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $103,600 and $192,400 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-10075908

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List of links present in page

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