Quality External Relationship Manager

Job ID
REQ-10027671

11月 22, 2024

USA

摘要

The Cell and Gene Therapy External Quality Lead (CGT) Lead will be responsible for leading and managing the external quality assurance, ensuring compliance with global quality standards and regulatory requirements. This role oversees quality-related activities with external partners, including Contract Manufacturing Organizations (CMOs) and suppliers, and develops and implements supplier quality management strategies. The role holds these responsibilities in the Cell and Gene Therapy manufacturing plants.
This role can be located on-site in Morris Plains, NJ or Durham, NC. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.

Location: Morris Plains NJ or Durham, NC LI-#hybrid

About the Role

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Key Responsibilities:

- **External Quality Management:** Lead and manage the external quality assurance team, ensuring compliance with global quality standards and regulatory requirements. Oversee quality-related activities with external partners, including CMOs and suppliers.
- **Supplier Quality Management:** Develop and implement supplier quality management strategies. Participate in supplier audits, manage discrepant material escalations, and ensure effective communication and collaboration with suppliers.
- **External Partnerships Management:** Collaborate with and manage external partnerships, including material suppliers, service providers, and CMO stakeholders. Ensure the establishment and management of quality-related agreements.
- **CMO Quality Activities Support:** Govern Key Quality Indicators (KQIs) as defined in agreements and act as a front-facing leader to CMO partners, ensuring effective communication and collaboration.
- **Firewall Administration Governance:** Oversee the administration of firewalls to ensure secure and compliant operations.
- **Compliance and Documentation:** Ensure all quality-related documentation is accurate, up-to-date, and compliant with internal and external regulatory standards. Manage quality-related agreements and oversee change control processes.
- **Metrics and Reporting:** Provide regular metrics and trending reports on quality performance. Identify critical compliance and business-related issues and develop remediation strategies using a risk management approach.
- **Stakeholder Collaboration:** Partner with internal stakeholders such as supply chain, manufacturing operations, regulatory affairs, and global quality functions to support and execute quality initiatives. Act as a front-facing leader to CMO partners and manage escalations related to external quality issues.
- **Inspection Support**: Support onsite inspections and ensure the facility is inspection-ready.
- **Compliance and Business Issue Resolution:** Identify critical compliance and business-related issues related to the supply of materials or services. Develop and implement remediation strategies using a risk management-based approach.
- **Escalations and Inspections Leadership:** Lead escalations related to external quality for critical issues and support onsite inspections to ensure compliance and readiness.

Essential Requirements:

- A Bachelor ' s degree in scientific or technical field preferably in Chemistry, Biology, Engineering, or a similar discipline
- 10 years ' experience in biopharmaceutical based GMP manufacturing operations quality assurance including direct experience in external management programs for biotechnology manufacturing facilities
- Proven track record in supplier quality management and external quality assurance.
- Experience in managing quality-related activities with Contract Manufacturing Organizations (CMOs) and suppliers.

The pay range for this position at commencement of employment is expected to be between $158,400 and $237,600 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

站点
Morris Plains

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
Durham, USA

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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REQ-10027671

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