Specialist, Quality Control Microbiology

Job ID
REQ-10068269

12月 18, 2025

USA

摘要

Manage Quality aspects of clinical programs and projects within area of responsibility. Ensure and support overall GxP conformity and Compliance with the Novartis Quality Management Systems. Identify and execute on OpEx opportunities. Build/manage stakeholder relationships and expectations

About the Role

Location: Durham, NC

#LI-Onsite

Please note this role is on-site 5 days a week and does not have the ability to work remotely. This

role is based in Durham, NC. Novartis is unable to offer relocation support for this role: ***please only apply if this location is accessible for you.***

Major accountabilities:

- Ensures the timely collection, monitoring, and reporting of Quality Key Performance Indicators (KPIs) for management reporting -Assists in Health Authority inspections and internal audits by supplying information and documentation in a timely manner -Support and track the implementation and maintenance of the local Quality system in in accordance with the Novartis Quality Manual -Manages processes and systems for all GxP Quality Assurance e.g. Change control, Training Management, Escalation Management, Risk Management.
- Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.
- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Ensures adequate tracking and on time completion of corrective and preventive actions (CAPA), inc escalation of issue related to the closure of CAPA, as appropriate.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments -Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation Supports Compliance review of projects and inspection readiness and management -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- In accordance with departmental objectives such as support of projects with agreed quality and delivery date -passing of internal and external inspections.
- Maintain sound working relationships with partners and customers -Demonstrated/recognized leader of specific GxP; early external/industry engagement -Basic financial knowledge (e.g., cost management, budget forecast, etc.) -Role Model of Novartis culture, values & behaviors for his/her department

Minimum Requirements:

Work Experience:

- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Agility.
- Audit Management.
- Business Partnering.
- Change Control.
- Continuous Learning.
- Health Authorities.
- Influencing Skills.
- Knowledge Of Capa.
- Qa (Quality Assurance).
- Quality Management.
- Quality Management Systems (Qms).
- Risk Management.
- Root Cause Analysis (Rca).
- Self Awareness.
- Sop (Standard Operating Procedure).
- Technological Expertise.

Languages :

- English.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $77,000 and $143,000 per year. 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.

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

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.

部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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