

Quality Assurance Manager - QP/RP

Job ID
REQ-10022031

11月 05, 2024

Netherlands

摘要

Location: The Netherlands, Amsterdam

As Quality Assurance Manager - QP/RP you will assure that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements and you will ensure that relevant documentation is up-to-date and archived correctly. Furthermore you will be responsible for the “state of the art” GxP know-how and future trends in the field of GxP.

About the Role

Major accountabilities:

- Ensure that all aspects of the handling, manufacturing and distribution of bio-pharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective

Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.

- Review and archive batch documentation, conduct self-inspections, and monitor corrective actions
- Conduct GxP monitoring, investigate noncompliance, and manage critical quality issues
- Escalate issues per Novartis escalation policy and initiate market actions if required
- Assess quality trends and drive continuous improvement for processes and product quality
- Maintain contacts with regulatory authorities and stay updated on GxP regulations
- Support product launches in collaboration with partners and development organizations
- Ensure drug products are released in accordance with specifications and regulations
- Maintain coordinated contact with regulatory certified QP and RP

Minimum Requirements:

- Education: Bachelor ' s Degree or equivalent 4-Year University degree in a Scientific or Technology field (e.g. Chemistry, Pharmacy or other Life Science). Advanced degree preferred.
- 3+ years of relevant experience in a Pharmaceutical Industry across Quality Commercial/Quality Operations/Manufacturing/Development.
- Certified Qualified Person (QP) and Responsible Person (RP).
- Solid communication skills and problem solving capabilities
- Fluency in English (oral and written), additional language is plus.

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>

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You will receive: Competitive salary, Annual bonus, Pension scheme, Share scheme, Health insurance, 27 days annual leave, Flexible working arrangements, subsidized dining facilities, Employee recognition scheme, learning and development opportunities.

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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部门
Operations

Business Unit
Innovative Medicines

地点
Netherlands

站点
Amsterdam

Company / Legal Entity
NL08 (FCRS = NL008) Novartis Pharma NL

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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