

Quality Assurance Manager & Responsible Person (Part-time)

Job ID
REQ-10057898

7月 16, 2025

Hungary

摘要

As QA Manager & Responsible Person you will particularly focusing on Radiopharmaceuticals. In this role you will release Novartis human medicinal products in accordance with the GDP regulations, relying on the final sample/withdrawal/suspension notifications on the NNGYK website.

As Deputy of Radiosafety Officer Person you will be solely acting in Novartis Hungary according to the local legal requirements and be responsible for release for distribution of Radiopharmaceuticals (radioisotope labeled medicinal products directly delivered to the hospital centers), handling product related documents and informing the specific wholesaler by preparing and issuing the necessary document intended for product release.

About the Role

This position is part-time (50%) and requires flexible working hours.

Major accountabilities:

- Part-time Responsible person position is responsible for maintaining GDP license for RLT and gene-therapy arrivals and human medicinal product release.
- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / 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.
- Prepare, review and check the batch documentation for correctness, completeness and safely archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, monitoring and following up the corrective actions accordingly.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.
- Ensure investigations are correctly executed, and that all required actions are taken appropriately and in a timely manner. Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required.
- Perform assessments and manage filing accordingly as well as ensure that Change requests are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Pharmaceutical authorities in respect to up-dated Quality Assurance Manager & Responsible Person.

Minimum Requirements:

- Education: Pharmacist degree and at least 1 year experience at a Hungarian human medicinal product Wholesaler in QA position is a requirement.
- 3-5 years experience in Pharma/Wholesaler sector in a GMP/GDP environment/equivalent
- Operations Management and Execution experience. Working experience within pharmaceutical industry is key.
- Knowledge of Good Distribution Practice, Inspection preparations, CAPA, GMP, Product release, Quality control and industry IT systems (e.g. SAP).
- Hungarian and English language - both languages required at Proficiency level.
- Driving Licence B and Hungarian based location

Minimum Requirements

- Responsible Person and/or Radiosafety Responsible Person experience.
- Experience in Manufacturing sector in analytical lab in a GMP and/or ISO environment is highly valued.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people ' s lives and our

vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards> 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.

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>

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.

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>

部门
Operations

Business Unit
Innovative Medicines

地点
Hungary

站点
Budapest

Company / Legal Entity
HU02 (FCRS = HU002) Novartis Hungary

Functional Area
Quality

Job Type
Part time

Employment Type
Regular

Shift Work
No

[Apply to Job](#)

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



Job ID
REQ-10057898

Quality Assurance Manager & Responsible Person (Part-time)

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10057898-quality-assurance-manager-responsible-person-part-time>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/about/strategy/people-and-culture>
3. <https://talentnetwork.novartis.com/network>
4. <https://www.novartis.com/careers/benefits-rewards>
5. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Budapest/Quality-Assurance-Manager---Responsible-Person--Part-time-REQ-10057898>
6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Budapest/Quality-Assurance-Manager---Responsible-Person--Part-time-REQ-10057898>