PART-TIME QA Manager & Responsible Person

Job ID
REQ-10004347
Jun 10, 2024
Hungary

Summary

Novartis is the number one innovative company in Hungary, and this is your opportunity to join us as the QA (GDP) Manager & Responsible Person 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), handling product related documents and informing the specific wholesaler by preparing and issuing the necessary radiosafety certificate intended for product release. This position is part-time (50%) and requires flexible working hours.

About the Role

Your key responsibilities:
Your responsibilities include, but are not limited to:

- Quality oversight of the work in the Novartis warehouse area according to GMP and GDP Guidance in compliance with the local regulations related to the activity. This includes inspecting the sampling process, qualification, and release of registered medicinal products entering the warehouse, and in the case of non-compliant products: the blocking of these products in the computerized system (SAP and its relevant cloud based applications).
- Manage quality certificates electronically signed by the EU Qualified person of Novartis to be sent to wholesale partners; keep records of suppliers and customers and regularly review them; approve the change / validation / qualification documents for all significant changes in the wholesaling process.
- Maintain appropriate documentation and checking of the temperature recorders (data loggers) applied during delivery and wholesale in-and out-bounding; Also responsible for initiating and supervising product recall: implement necessary measures in case of recall and product suspension; handle customer complaints and quality complaints in close collaboration with Novartis Complaint Manager and Complaint Hub
- Follow the changes in the regulations affecting respective field. Prepare and review quality assurance regulatory documents in the field of regulation of activities related to pharmaceutical wholesale activities; participate in professional GMP/GDP/ISO trainings and perform GMP/GDP/ISO trainings
- Report, investigate and document any discrepancies related to the wholesaling and warehousing activity of the medicinal products subject to the Hungarian market; manage annual self-inspection plan, participate in their implementation; preparation for and active participation in official Authorities (e.g.

NNGYK) inspections (especially with regard to radiopharmaceuticals), participate in external audits if necessary

- Handle formally defective HA permits (so called faulty sample permits), final sample permits, contact the responsible quality assurance and Regulatory Affairs of Novartis Hungary Ltd.; receive, inspect, qualify and release printed packaging materials and concerning units subject of modification with the permission of NNGYK. Approve the packaging order of these preparations to be modified - review of the packaging documentation, control of the repacked/modified units and their packaging material provided by our third party packaging plant.

What you'll bring to the role:

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

Desirable Requirements:

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

Why consider Novartis?

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

We offer a market-competitive base salary in line with your qualification, experience, and individual competencies. Additionally, we offer an attractive incentive program, learning & development options, and worldwide career opportunities within the Novartis group.
Novartis are an equal opportunities employer and welcome applications from all suitably qualified persons.

Imagine what you could do here at Novartis!

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

Division
Operations
Business Unit
Innovative Medicines
Location
Hungary
Site
Budapest
Company / Legal Entity
HU02 (FCRS = HU002) Novartis Hungary
Functional Area
Quality
Job Type
Part time
Employment Type
Regular
Shift Work
No
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