Quality Assurance Manager & QP

Job ID
REQ-10015396
Jul 23, 2024
Romania

Summary

The Quality Operations Manager/QP has direct collaboration and partnership with all associates for implementation of the Novartis Quality Manual and Quality Management System in the CPO, to achieve a high level of quality and compliance. As a Qualified Person / Deputy Responsible Person/ Quality Asurance Manager you are responsible with Coordination of the Quality Assurance activities within the local organization, in order to ensure that all aspects related to its operational activities are in accordance with the legal regulations GDP and GMP (GxP) and with the Procedures and Quality Manual within Novartis Pharma Services Romania

About the Role

MAIN ACCOUNTABILITIES:

- Handling complaints, deviations, CAPAs, support recalls, destructions, and archiving according to the Novartis Quality Manual and local/global written procedures.
- Perform Duty of care check for our drugs products as the QP registered in our GMP License
- Supporting GxP Quality Manual implementation, included but not limited to tracking of QA Manual implementation, writing/reviewing of LWPs/LPs as assigned by CPO QA Head.
- Handling the local and global SOPs relevant for the Romania Organization
- Maintaining current knowledge of relevant regulatory and legislative requirements and trends.
- Ensuring, together with Country QA Head, previous preparation and facilitate the conduct and coordinate the follow-up of GxP related Health Authority inspections and internal audits at CPO level, vendor level and investigator sites.
- Supporting Country QA Head in all GxP related activities as needed during absence of QA Managers/QPs.
- Being responsible for implementing specific QA projects and reporting the related actions to Country QA Head.
- Conducting proactive in-process quality and compliance review through monitoring of adequate Key Quality Indicators (KQIs) and assuring that gaps are addressed appropriately in order to mitigate risk;
- Providing training to associates within the company, regarding local/ global quality assurance procedure.

- Ensures that all aspects of the distribution of medicinal products for human use are carried out in compliance with the legislation in force, the policies and requirements of the Novartis quality manual;

Role Requirements:

- Qualified person certificate by ANMDMR for drugs - it’s mandatory
- Degree in Pharmacy or related fields (such as Medicine, Biochemistry, Chemical engineering);
- Proficiency in English, both written and spoken;
- Minimum 1 year of experience in the pharmaceutical industry in quality assurance/ regulatory affairs
- Proven knowledge of legislation, the quality assurance management systems and the GxP area
- Experience in handling complaints and deviations, implementing projects
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769 million lives were touched by Novartis medicines in 2020, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

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.

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Innovative Medicines
Location
Romania
Site
Bucuresti
Company / Legal Entity

RO07 (FCRS = RO007) NOVARTIS PHARMA SERVICES ROMANIA S.R.L
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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