

Country Quality Specialist, QP Delegate/RP Deputy

Job ID
REQ-10033966

12月 18, 2024

Denmark

摘要

The Country Quality Specialist, QP Delegate/RP Deputy manages Quality aspects and projects within area of responsibility. Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems. Furthermore, this role includes:

- Acting as QA Manager for Novartis Country Quality in Denmark for GMP/GDP related activities.
- Acting as the Qualified Person (QP) delegate for Novartis Healthcare A/S
- Acting as Responsible Person (RP) deputy for Novartis Healthcare A/S

About the Role

Major accountabilities:

- Release commercial medicines for distribution after QP certification
- Ensure that CoCs/CoAs and other documents are reviewed and archived for all batches released for sale

- Ensure escalations of GMP related issue.
- Act as the Responsible Person deputy for the Wholesale Distribution Authorization in Denmark
- Coordinating and promptly performing any recall and mock recalls for medicinal products
- Ensure that Product Technical Complaints concerning Novartis products are appropriately reported and investigated according to regulation.
- FMD alert handling oversight
- Report stock outs to Country Agency

Minimum Requirements:

- Education: Degree in Life Sciences or related fields. Eligible to act as Qualified Person (QP). EU QP qualifications must be effective and recognized by local regulations.
- At least 1 year of experience in the pharmaceutical industry in a relevant field such as quality assurance, quality control, registration, clinical development, or production or a directly related area.
- Solid GxP knowledge
- Quality mindset, analytical approach, self-driven and collaborative
- Fluent English, written and spoken

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部门

Operations

Business Unit

Innovative Medicines

地点

Denmark

站点

Copenhagen

Company / Legal Entity

DK06 (FCRS = DK006) Novartis Healthcare A/S

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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