

Country Quality Specialist, QP Delegate/RP Deputy

Job ID
REQ-10033966
Dec 18, 2024
Denmark

Summary

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

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>

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Division

Operations

Business Unit

Innovative Medicines

Location

Denmark

Site

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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