Associate Director QA Evaluation and Integration

Job ID
REQ-10058617

8月 05, 2025

Spain

摘要

The purpose of Associate Director QA Evaluation and Integration (QE&I) is to lead the end-to-end Evaluation of “In-licensing (BD&L)” and “Merger/ Acquisition (M&A)” up to the Integration of the acquired or in-licensed asset into the Novartis network.

Strong focus to act as Quality Integration Lead (QIL) to lead the Quality integration of an acquired or in-licensed asset into the Novartis network.

In line with the Novartis Quality standards, the QIL will establish a robust Quality Integration plan with directions of QA Line functions, members of the Quality Integration Team, and collaboration with the Quality organization at the acquired company or at the licensing partner. He/she will ensure timely execution of quality integration activities and will report progress to the Quality Integration Office and Integration Governance Boards, including on related remediation plans usually submitted as Novartis commitments to various Health Authorities.

Facilitate timely decision making by QA Management including relevant line functions based on recommendation from QA SMEs and business evaluation for the holistic QA assessment covering the due diligence (DD) evaluation as well as the QA integration activities for potential external

opportunities.

About the Role

Major accountabilities:

- Ensure that Novartis ' Quality Management Systems and applicable GxP rules (FDA, EMA and other Health Authorities) are embedded in acquired or in-licensed assets.
- Set up a Quality Integration Team consisting of QA Line functions, and develop, lead and coordinate quality integration activities starting with handover from DD QA, Integration Planning, Integration Execution and Reporting.
- Establish a robust Quality Integration plan with QA Line functions, members of the Quality Integration Team, and collaboration with the Quality organization at the acquired company or at the licensing partner. Ensure that risk mitigation measures from Due Diligence reports and related Quality risk analyses are included in the Quality Integration Plan.
- Ensure that Novartis ' Quality Management Systems and applicable GxP rules are embedded in the acquired company.
- Coordinate and compile the data for the development of the Quality Integration Budget for integration of an acquired or in-licensed asset.
- Ensure open and effective communication and business partnership with all stakeholders.
- Oversee the implementation and handover of deals by QA SMEs to the relevant LF. Provide the Quality and Technical expertise needed in the Quality Integration process or facilitate input from SMEs where specialist knowledge is required.
- Prioritizes, resolves issues and ensures escalation to management.
- Establish and lead cross-functional teams and act as single point of contact for BD&L DD QA and support QA assessments for corporate M&A and integration projects as required. Ensure representation of QA SMEs for all necessary functions.
- Ensures comprehensive due diligence assessments across all QA LF and timely recommendation to BD&L and M&A.
- Represent QA at BD&L DD relevant forums as determined by management
- Support Health Authority Inspection readiness programs as well as internal/external audits.
- Contribute to the continuous improvement within area of responsibility.

Minimum Requirements:

- Graduate in Chemistry, Pharmacy / Biotechnology, Microbiology or another related science or equivalent experience.
- Minimum 10 years ' experience in the pharmaceutical industry, including operative experience in QA, Production/Technical Operations/R&D, including at least 5 years in Quality. Demonstrated GxP experience.
- Broad understanding of global expectations of health Authorities in GxP regulated areas.
- 5 or more years of demonstrated leadership and accomplishments in an (international) matrix organization.
- Fluent English, written and spoken.

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部门
Development

Business Unit

Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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