# Director QA Evaluation and Integration

Job ID
REQ-10031816

12月 11, 2024

Spain

## 摘要

The purpose of QA (GxP) Director QA Evaluation and Integration 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. In this role, you will 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:**

- Establish and lead cross-functional teams and act as single point of contact for BD&L DD QA and support QA easements for corporate M&A and integration as required. Ensure representation of QA SMEs from / for all necessary functions.

- Ensures comprehensive due diligence assessments across all QA LF and timely recommendation to BD&L and M&A.
- 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 acquired or in-licensed assets.
- 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.
- Prioritizes, resolves issues and ensures alignment with QA LF head, including escalation to management.
- Represent QA at BD&L DD relevant forums including but not limited to, BD&L/M&A integration Quality Review Boards (QRBs), deputize for Global Head Business Development QA where required.
- Support Health Authority Inspection readiness programs as well as internal/external audits.
- Contribute to the continuous improvement within area of responsibility.

**Minimum Requirements:**

- Education: Graduate in Chemistry, Pharmacy / Biotechnology, Microbiology or another related science or equivalent experience
- Minimum 15 years' experience in the pharmaceutical industry, including operative experience in QA, Production/Technical Operations, 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 spoken and written English. Additional languages a plus

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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.

Alternative Location 1
Dublin (Country President Office (CPO)), Ireland

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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