

Director QA Evaluation and Integration

Job ID
REQ-10031816
déc 11, 2024
Espagne

Résumé

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

Why consider Novartis?

236 million. That's how many lives our products touched in 2022. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

Imagine what you could do at Novartis!

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration, and empowers our people to unleash their full potential.

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<https://talentnetwork.novartis.com/network>

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

<https://www.novartis.com/about/strategy/people-and-culture>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Development

Business Unit

Innovative Medicines

Emplacement

Espagne

Site

Barcelona Gran Vía

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A. 2/3

Alternative Location 1

Dublin (Country President Office (CPO)), Irlande

Functional Area

Qualité

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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