

Research & Development Quality Risk Management Manager

Job ID 394206BR Jun 21, 2024 Spain

Summary

R&D Quality Risk Management Manager, Location: Barcelona, hybrid onsite, #LI-Hybrid. As Research & Development Quality (RDQ) representative, you will support Regulatory Risk and Compliance by providing expertise and guidance to ensure that risk management process and governance is fit for purpose and meet Novartis standards and Health Authorities expectations. Engaging with R&D business, QA and ERM risk teams, and quality partners to advocate quality mindset and ensure RDQ risk management is executed with the highest quality. Though there is a preference for pharmaceutical knowledge, applications with the relevant Risk experience from other disciplines are welcome.

About the Role

Key Responsibilities:

- Supports RDQ risk management within RDQ, including management of the risk documentation, governance structure, and support meetings.
- Provide guidance and expertise to QA and business partners on risk identification, root cause analysis, lifecycle management, and risk documentation to ensure robust risk management.
- Proactively identifies quality risks to ensure appropriate risk identification, awareness, and risk management within RDQ.
- Support the enhancement of the appropriate governance and processes for management of significant risks and issues in RDQ.
- Continuously seek improvements and development of comprehensive systems and tools to support the RDQ risk management process.
- Develop and deliver training to ensure adherence to risk management standards. Foster a culture of collaboration and capability building by delivering educational and learning preparations (e.g. training, lessons learned, regular meetings with internal and external partners/ stakeholders).
- Provide GxP expertise and guidance on process excellence and projects across R&D/RDQ related to GxP regulations and standards.
- Participate in cross-functional / cross-divisional strategic initiatives to drive risk management excellence, performance excellence, quality and innovation.

Essential Requirements:

- Bachelor's degree in Life Sciences or business
- Excellent English language skills (oral and written)
- Significant relevant work experience in Risk Management
- Strong background and experience in GXP and relevant Health Authority regulations, paired with good

business understanding.

- Ability to be innovative when faced with opportunities or challenges.
- Strong mindset on in continuous improvement with effective change management skills to sustain a culture of high ethical standards and compliance.
- Excellence in communicating effectively across different audiences and organizational levels and the ability to bridge between quality, scientific and business experts to form strong and effective relationships with partners.
- High awareness of trends and ability to proactively address needs based on external demands.

Desirable Requirements:

- Experience gained in the pharmaceutical industry or public health sector, in the area of Drug Development.
- Experience presenting to and networking with senior leaders/stake holders to build strong collaboration.

Why Novartis?

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Division

Development

Business Unit

Innovative Medicines

Location

Spain

Site

Barcelona Gran Vía

Company / Legal Entity

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

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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