Associate Director, Medical Governance & Risk Management

Job ID
REQ-10041551
Μαι 28, 2025
Spain

Περίληψη

LOCATION: Barcelona, London or Dublin

The Associate Director of Medical Governance & Risk Management has a crucial role in supporting the implementation of the established unified governance framework for medical and patient-focused programs within our organization. This role is responsible for facilitating the roll-out of GxP processes, supporting self-assessments and audits, managing CAPA, and guiding associates in quality issue management. The Associate Director will actively contribute to maintaining excellence in risk and quality management within Novartis Medical Affairs

About the Role

Major accountabilities:

- Provide support in the implementation of the established unified governance framework for medical and patient-focused programs. Leverage the centralized Medical Excellence Governance Board (MEGB) to streamline consultation and escalation pathways for local and global Medical Affairs organizations
- Facilitate connections between local Medical Governance Leads (MGLs) and global experts within MEOG and Global Medical Affairs (GMA), contributing to onboarding, skill development, and effective communication flow.
- Assist in the development and execution of comprehensive self-assessments and controls in Medical Affairs, analyzing trends and findings, and providing insights for continuous improvement.
- Support audits by assisting in the preparation, conduction, and management of corrective and preventive actions (CAPA) in accordance with the yearly quality audit plan.
- Guide and mentor associates in managing risks and quality issues, ensuring alignment with risk and quality management practices. Assist GMA associates, through the role of Business Functional Representative (BFR/Quality Issue owner), contributing to investigations and ensuring proper management of CAPA for end-to-end resolution.
- Contribute to the development and updates on GxP processes, medical policies and guidelines, global business processes and procedural documents.
- Stay updated on industry trends and external demands to proactively address compliance needs. Assist in ensuring compliance with medical governance regulations, health authority requirements, and ICH guidelines. Ensure monitoring of training compliance for GMA associates.
- Collaborate with cross-functional teams to drive projects and achieve outstanding results. Support initiatives for creating stronger organizations and a culture of high ethical standards and compliance.

- Collaborate with the Medical capabilities function to ensure effective training and onboarding processes for MGL, MEOG and Medical Affairs associates.
- Act as a key stakeholder in decision-making processes and actively participate in project teams to drive outstanding results.
- Demonstrate strong leadership skills and the ability to work across functions, countries, and cultures.
- Utilize strategic, analytical, organizational, and planning skills to support the implementation of the governance framework.
- Act as a liaison between scientific and business functions, fostering collaboration and effective communication.
- Possess a strong business strategy acumen to align the medical governance and risk management with organizational goals and objectives

Key performance indicators:

- Quality Management System standards are maintained; potential risks are identified and mitigated for assigned areas; continuous improvement is ensured for own processes
- Health Authority inspections and internal audits have no critical findings in assigned areas due to lack of global governance

Minimum Requirements:
Work Experience and skills:

- Bachelor's degree in a relevant field (e.g., Medical Sciences, Life Sciences, Medicine or related fields)
- Minimum of 10 years of experience in the pharmaceutical industry, preferably in medical affairs, clinical development, medical compliance/Governance, quality assurance, risk management, regulatory, or a related area. Experience in more than one of these areas is desirable.
- Strong knowledge of GxP processes and medical guidelines. Deep understanding of health authority requirements and ICH guidelines.
- Experience in self-assessments, audits, and managing CAPA.
- Ability to contribute to effective risk management and collaborative problem-solving.
- Experience in working with global teams and cross-functional collaboration. Demonstrated capability to work across functions, countries, and cultures. Previous experience in a country and/or cluster/regional role required.
- Proven experience in driving change, building capabilities, and sustaining a culture of high ethical standards and compliance.
- Strong track record of implementing strategy effectively.
- Excellent leadership and interpersonal skills, capable of problem-solving, negotiation, and conflict resolution.
- Proactive and able to quickly identify contingency plans.
- Strong strategic, analytical, organizational, and planning skills.
- Proven ability to act independently while incorporating stakeholder feedback.
- Able to influence decision-making and drive project teams for outstanding results.
- Possess facilitation skills to bridge between scientific and business functions and enable effective cross-functional collaboration.
- Business strategy acumen to contribute to the alignment of medical governance and risk management with organizational goals and objectives.

Languages :

- Fluent in English, both in speaking and writing.

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International
Business Unit
Innovative Medicines
Τοποθεσία
Spain
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Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Dublin (NOCC), Ireland
Alternative Location 2
London (The Westworks), United Kingdom
Functional Area
Research & Development
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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