

R&D Quality Incident Manager (m/f/d)

Job ID
REQ-10028774
Jan. 22, 2025
Spanien

Zusammenfassung

R&D Quality Incident Manager (m/f/d)

Location: Barcelona Gran Vía, Spain #LI-Hybrid

RDQ Incident Management is a centralized team governing major and critical quality incidents requiring escalation. The RDQ Incident Manager (m/f/d) will drive the assessments of quality issues raised in Research and Development to ensure appropriate escalation, notification, categorization, mitigation, and health authority reporting, as well as consistency in assessment and documentation for all quality incidents. The RDQ Incident Manager (m/f/d) will be the key liaison between quality and business stakeholders to ensure satisfactory management of quality issues.

About the Role

Major accountabilities:

Your responsibilities will be but are not limited to:

- Ensure consistency in incident management process, and drive decisions on escalation, criticality, categorization of quality issues.
- Key SME on QEM system/process, as well as Key point of contact for guidance on QI process and determination of issue criticality and categorization of issues, next steps, and mitigating actions
- Governance of all QIs to ensure consistent process and adherence to QIM procedure.
- Prepare pre-reads/presentation and meeting minutes with issue owner.
- Provide oversight of QEM records not in scope with periodic review of records to evaluate adherence to IMT principles to ensure consistent approach.
- Lead and manage Health Authority reporting as needed to ensure reporting is completed in a compliant manner and that Novartis assures adequate responses to Health Authority inquiries.
- Support audits and inspections as needed.

Minimum requirements:

- Education: Minimum degree in Science, Engineering or relevant discipline.
- 8+ years industry experience specifically in clinical operations and clinical site management with a strong understanding of clinical research international standards and regulatory requirements from Health Authorities.
- Ability to work effectively in a matrix cross-functional environment, and strong capacity for working independently with minimal guidance.

- Ability to make & communicate difficult decisions, associated with strong written and verbal communication skills.
- English proficiency.

Desirable requirements:

- Audits and inspections experience highly desirable.

Benefits & Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: [Novartis Life Handbook](#)

Benefits in Spain include Company Pension plan; Life and Accidental Insurance; Meals; Allowance or Canteen in the office; Flexible working hours.

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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>

Abteilung

Development

Business Unit

Innovative Medicines

Ort

Spanien

Website

Barcelona Gran Vía

Company / Legal Entity

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

Alternative Location 1

Home Worker, Vereinigtes Königreich

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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