NOVARTIS

Clinical Quality Assurance Operations Manager

Job ID
REQ-10061938

9月 24, 2025

Spain

摘要

LOCATION: London, UK, Dublin, Rep of Ireland or Barcelona, Spain
ROLE TYPE: Hybrid Working, #LI-Hybrid

As a Clinical Quality Assurance Operations Manager you will provide resource management and Quality deliverable oversight on the end-to-end Clinical Trial Process for the Clinical Quality Assurance (CQA) Process Quality and Compliance team to ensure compliance with the Health Authorities requirements, the internal standards and a full adherence to patients ’ safety, rights and well-being.

About the Role

Job Description

Developing, implementing, and executing CQA project management to support department resource

management and on-time completion of tasks. The CQA Operations Manager will lead regular project update meetings with CQA personnel to track CQA projects and initiatives, time requirements for tasks, and adjustments to resources based on program needs.

They will also provide regular updates to CQA management regarding CQA resource activities and changing resource needs. Lead project management oversight and scheduling for CQA projects separate from DU CQA support activities. And drive a culture of quality in Development by close business collaborating to positively impact the business and implementing the Strategy, Mission and Vision of Research and Development Quality (RDQ).

Key Responsibilities:

- Use project management tools to design templates/tools for the tracking of CQA tasks and deliverables relevant to CQA Process Quality and Compliance support activities.
- Support maintenance of CQA documentation, including GxP record archiving in relevant systems
- Ensure maintenance of CQA training curricula in the applicable systems
- Conduct regular project management meetings with CQA associates to ensure availability of current CQA resource information and program milestone dates.
- Use project management tracking tools to provide regular CQA resource utilization information to CQA management.
- Provide project management oversight to non-Development Unit (DU) CQA projects and workstreams to ensure timely completion of tasks and CQA resource oversight.
- Facilitate unified quality audit program (UQAP) planning in CQA, act as CQA Responsible person for
  Investigator Site Audit (ISA) target identification and reporting
- Interface with RDQ and Development line functions for CQA resource planning related to cross departmental initiatives

Essential Requirements:

- +7 years of involvement in regulated activities (Good Clinical Practice (GCP)/Pharmacovigilance (PV)), clinical development and/or QA positions.
- Broad understanding of global expectations of Health Authorities in Clinical Development and profound understanding of the science of product development.
- Ability to work independently and in a global/matrix environment.
- 3 or more years ' experience in managing projects.
- Ability to effectively interact with and present to senior management at all levels, as well as to external audiences and inspectors.
- Strong skills in GCP, quality and/or clinical development.
- Strong interpersonal, communication, negotiation, and problem-solving skills.
- Ability to interact with and present information to management, and diverse audiences.

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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部门
Development

Business Unit
Quality

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 (NOCC), Ireland

Alternative Location 2
London (The Westworks), United Kingdom

Functional Area
Quality

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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