Development QA Manager

Job ID
REQ-10044224

3月 27, 2025

Spain

摘要

Proporcionar experiencia en garant í a de calidad, orientaci ó n y apoyo a las actividades operativas en organizaciones de desarrollo e investigaci ó n para garantizar el cumplimiento de los requisitos reglamentarios aplicables y los procedimientos y est á ndares de calidad de Novartis.
Gestionar proyectos, incluidas las iniciativas del Plan de Calidad, y los procesos que respaldan los objetivos de calidad para garantizar su cumplimiento con las regulaciones de GxP.

About the Role

Location: Barcelona, Spain

Working model: Hybrid working model (which requires 12 days per month in the office)

Note: Novartis is not able to offer relocation support for this role. Please only apply if this location is accessible for you.

This is a dynamic role and no two days are the same! You'll be constantly interacting with different stakeholders, tackling various cases related to diverse procedures and regulations. Your QA expertise will make you a go-to subject matter expert for colleagues and processes.

Joining us would be an opportunity to join a success story and become a part of it!

Key Responsibilities:

- Local Quality System: Oversee implementation, maintenance, and monitoring of the local Quality System and written procedures to ensure GCP and Pharmacovigilance related processes and tasks are compliant with Novartis global requirements and applicable regulations and guidelines.
- Quality Plan and Continuous Improvement: Support and monitor implementation of the local Quality Plan (QP) deliverables related to GCP and PV areas, ensuring alignment with the applicable global QP chapters wherever possible.
- Training systems: Ensure adequate training systems are in place in assigned country(ies) for GCP, GPvP and other relevant Development activities in compliance with Novartis global and local requirements. Assure that relevant business areas are maintaining inspection-ready documentation to support reviews of training compliance.
- Quality Issue Management: Drive Clinical/PV QA investigation activities at the country level as appropriate and ensure implementation of robust CAPA plans where applicable.
- Risk Identification and Management: Monitor local Quality System, processes and Key Quality Indicators (KQIs) to proactively identify potential quality risk. Collaborate with business partners to ensure that risks are reviewed for root cause, impact, and recurrence and assure that relevant line function owners put in place mitigation plans to address.
- Inspection Management and Support: Provide leadership and/or support as needed for GCP and GPvP HA inspections of activities in assigned country(ies). Assure support prior to, during and post inspection for the country organization, investigational sites and/or external service providers, as applicable, in collaboration with the assigned inspection lead.
- Audit Management: Partner with local and global Development teams, PS, NCQ and other internal stakeholders in the execution, where QA processes are subject to the audit, and follow-up of audits on clinical development and PV activities.
- CAPA management: Act as local approver for the documentation and management of local CAPAs to support appropriate review and closure of each corrective and preventive action.

Role Requirements:

- Degree in Life Sciences or Health Science.
- 5+ years of pharmaceutical industry experience with significant experience in pharma drug development in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area.
- At least 3 years of experience in clinical development.
- Experience with project management and leading projects

- Fluent English (both spoken and written)

Additional beneficial skills:

- Fluent Spanish would be an advantage

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
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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