Clinical Quality Assurance - Program Lead

Job ID
REQ-10061165

9月 10, 2025

Spain

摘要

-Bieten Sie Qualit ä tssicherung und Compliance-Aufsicht f ü r Entwicklungs- und Forschungsfunktionen. F ö rdern Sie die Ü berwachung von Qualit ä tsmanagementsystemen und -initiativen innerhalb der globalen, regionalen und L ä nderorganisation und stellen Sie die Einhaltung der geltenden regulatorischen Anforderungen der Gesundheitsbeh ö rden (z. B. GCP, GLP, GMP, PV, IP) und der Novartis-Verfahren und Qualit ä tsstandards sicher. Vorbild f ü r gutes Qualit ä tsverhalten bei gleichzeitiger F ö rderung einer Qualit ä tskultur (z. B. richtiges erstes Mal usw.), um die nicht-qualitativ hochwertigen Stakeholder (z. B. NIBR, GDD) positiv zu beeinflussen. Entwickeln, vorantreiben und/oder unterst ü tzen Sie Qualit ä tsplaninitiativen, um Die Organisationsstrategie, Mission und Vision zu erreichen.

About the Role

Key Responsibilities:

- Proactively provide QA leadership to the business strategy for assigned programs/trials by ensuring considerable organization awareness (e.g. Interrelationship of departments and business priorities),
- Drive implementation of quality strategy within Global Clinical Team (GCT)/ Clinical Trial Team (CTT) under responsibility
- Regularly monitor the implementation of the annual Quality Plan pertaining to the assigned programs/studies
- Ensure adequate oversight of proactive quality risk management process in the overseen areas including quality risk assessments and submission/inspection readiness activities and ensure that Clinical Trial Process (CTP) are in control
- Provide robust and clear quality oversight in the following areas of clinical development:
    - Support/collaborate with key stakeholders (e.g., Country Development Quality (CDQ), Development Units (DUs), GCT and/or CTT members) to ensure that risks are detected and remediated.
    - Support core governance for quality incident management for critical and major deviations pertinent to the programs being assigned and ensure timely escalation when required.
    - Provide Good Clinical Practice (GCP) guidance to day-to-day questions arising from Clinical trials deliverables.
    - Collaborate with Country Development QA and External Service Providers (ESP) QA to drive initiatives relevant to internal monitoring and outsourced activities Quality oversight.
    - Support inspections preparation and facilitation in collaboration with other QA groups within Research & Development Quality (RDQ).
    - Support audits and inspections follow-up activities including Corrective & preventative Actions (CAPA) preparation.
- Actively leverage audit/inspection outcomes/trends to sustain improvement in clinical trials conduct.
- Active participation in continuous improvement initiatives (including Work streams) and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability
- Be QA point of contact for the defined trials and attend the meetings and ensure quality is embedded in the decision taking processes.

Essential Requirements:

- Bachelor ' s degree in life science or healthcare field required. Advanced degree or equivalent education/degree in life sciences/healthcare preferred (PhD/MD/ PharmD/ Masters).
- 7 years of involvement in regulated activities (GCP/ Pharmacovigilance (PV)), clinical development and/or QA positions.
- Broad understanding of global expectations of Health Authorities in the area of 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.
- Strong skills in GCP, quality and/or clinical development

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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.

Alternative Location 1
Basel (City), Switzerland

Alternative Location 2
Dublin (NOCC), Ireland

Alternative Location 3
Home Worker - England/Wales, United Kingdom

Alternative Location 4
London (The Westworks), United Kingdom

Functional Area
Quality

Job Type
Full time

Employment Type
Regul ä r

Shift Work
No

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